Supreme Court, U. S.
FILED
JUN 12 1979
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-1850

JAMES ROBERT PRIVITERA, JR.,

Petitioner,

v.

THE STATE OF CALIFORNIA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA

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INDEX

	Pages
OPINIONS BELOW	1
JURISDICTION	2
QUESTIONS PRESENTED	2 - 3
CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED	3 - 8
STATEMENT	8 - 10
REASONS FOR GRANTING THE PETITION	10 - 22
CONCLUSION	23
APPENDIX A (OPINION OF SUPREME COURT)	A1 - A110
APPENDIX B (ORDER ON PETITION FOR REHEARING)	B1
APPENDIX C (OPINION OF COURT OF APPEALS)	C1 - C120

CITATIONS

CASES:

Paul v. Davis (1976) 424 U.S. 693	10
Planned Parenthood of Central Missouri v. Danforth (1976) 428 U.S. 52	15,16,17
Roe v. Wade (1973) 410 U.S. 113	14,15,16
United States v. Rutherford No. 78-605, Oct. Term 1978	20,21,22

	Pages
Whalen v. Roe (1977) 429 U.S. 589	10,11,12
CONSTITUTIONAL PROVISIONS:	
UNITED STATES CONSTITUTION	
Amendment XIV	3
STATUTES	
Food, Drug and Cosmetic Act, Section 505 21 U.S.C. 355	5-8
California Health and Safety Code Section 1707.1	3-5

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TO THE SUPREME COURT OF CALIFORNIA

The petitioner, James Robert Privitera, Jr., respectfully prays that a writ of certiorari issue to review the judgment and opinion of the Supreme Court of the State of California rendered in these proceedings on March 15, 1979.

OPINIONS BELOW

The opinion of the Supreme Court (App. A, infra, pp. A1 - A110) is not yet reported. The order denying

petition for rehearing in the Supreme Court appears at Appendix B, infra, p. B-1. The opinion of the Court of Appeals (App. C, infra, pp. C1 - C120) is reported at 74 Cal.App. 3d 936, 141 Cal.Rptr. 764.

JURISDICTION

The judgment of the Supreme Court of California was entered on March 15, 1979. This petition for certiorari was filed less than 90 days from the date aforesaid. The jurisdiction of this Court is invoked under 28 U.S.C. § 1257(3).

QUESTIONS PRESENTED

1. Whether the imposition of criminal sanction on a licensed physician for prescribing laetrile as a cancer treatment for an informed consenting cancer patient, without first seeking governmental approval of its safety and effectiveness, serves a compelling state interest.

2. Whether denial of laetrile from a licensed physician to cancer patients who have unsuccessfully sought relief from conventional therapy and who are

fully informed as to the consensus of scientific opinion concerning laetrile is reasonably related to the preservation and protection of the public health.

CONSTITUTIONAL PROVISION AND STATUTES INVOLVED

Constitution of the United States, Amendment XIV, § 1:

"...nor shall any state deprive any person of life, liberty, or property without due process of law..."

California Health and Safety Code Section 1707.1 provides:

> The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 355], or (2) there has been approved an appli-

cation filed with the board setting forth:

(a) Full reports of investigations which have been made to show whether or not such drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use;

(b) A full list of the articles used as components of such drug, medicine, compound or devices;

(c) A full statement of the composition of such drug, medicine, compound or device;

(d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug, medicine or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation;

(e) such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and

(f) Specimens of the labeling and advertising proposed to be used for such drug, medicine, compound or device.

Section 505 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355, provides in part:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the applica-

tion (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use * * *

* * * * *

(d) If the Secretary finds * * * that (1) the investigations * * * required to be submitted to the Secretary * * * do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests * * * do not show that such drug is safe for use under such conditions; * * * (4) * * * he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) * * * there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling

thereof, or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. * * * As used in this subsection and subsection (e) of this section, the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it would fairly and responsibly be concluded by such experts that the drug will have effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * * * *

(i) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by

experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) The submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing. * * *.

STATEMENT

The petitioner, James Robert Privitera, Jr., a licensed medical doctor, was convicted by jury on December 16, 1975, of conspiring with his co-defendants to prescribe and sell laetrile to cancer patients for the alleviation or cure of cancer in violation of California Health and Safety Code Section 1707.1.

Dr. Privitera prescribed laetrile for cancer patients and referred patients to his co-defendants to buy laetrile.

All the cancer patients, whether state or defense witnesses, were knowledgeable persons fully aware of the nature of state sanctioned cancer therapies before seeking treatment from Dr. Privitera.

On November 10, 1977, the State Court of Appeal, Fourth District, reversed the judgment of the trial court and held that: (1) Section 1707.1 violated state and federal constitutional rights of privacy of the patient and the physician; (2) Section 1707.1 is not reasonably related to the expressed legislative purpose of preventing fraud; and (3) a search warrant was improperly issued and therefore invalid.

On March 15, 1979, a majority of the state Supreme Court reversed the Court of Appeal and held that: (1) Section 1707.1 did not violate state and federal constitutional rights of privacy, (2) Section 1707.1 bears a reasonable relationship in the achievement of the legitimate state interest in the health and safety of its citizens, and

(3) the search warrant issue was not preserved by appropriate objection below.

On April 12, 1979, the Supreme Court denied Dr. Privitera's petition for rehearing.

REASONS FOR GRANTING THE WRIT

1. The Court below has decided a federal question of substance in a way probably not in accord with applicable decisions of this Court.

In holding that a state can condition an informed individual's right to pursue a particular course of medical treatment from a licensed physican on state approval of that treatment, the California Supreme Court found no fundamental right of privacy or personal liberty involved and said: "But the kinds of 'important decisions' recognized by the high court to date as falling within the right of privacy involve 'matters relating to marriage, procreation, contraception, family relationships, and child rearing and education' (Whalen v. Roe, 429 U.S. at p. 600, FN.26, quoting Paul v. Davis (1976) 424 U.S. 693, 713),

but do not include medical treatment."

In Petitioner's view, the court below ignored the analysis of the Court in Whalen. This Court found in Whalen an implication of a privacy "interest in independence in making certain kinds of important decisions" in matters pertaining to the care of one's health. But the Court upheld the New York statutory scheme in Whalen because "neither the immediate nor the threatened impact" of the scheme on the "independence of patients for whom Schedule II drugs are medically indicated is sufficient to constitute an invasion of any right or liberty protected by the Fourteenth Amendment."

Before reaching this conclusion, the Court stated the following reasons:

> Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. Although the State no doubt could prohibit entirely the use of particular Schedule

II drugs, it has not done so. This case is therefore unlike those in which the Court held that a total prohibition of certain conduct was an impermissible depreva-tion of liberty. Nor does the State require access to these drugs to be conditioned on the consent of any state official or other third party. Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient.

In this case, the substance in question, laetrile, is not narcotic, habit forming, hallucinatory, or toxic such as the dangerous "Schedule II" drugs in Whalen. The state does require that access to laetrile be conditioned on the consent of state officials. The informed consenting cancer patient has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use

needed medication. The decision to prescribe, or to use, is left entirely to the prior approval of the state. This case is like those in which the Court held that a total prohibition of certain conduct was an impermissible deprivation of liberty.

The immediate impact of the decision is to deny treatment with an otherwise harmless substance to informed consenting individuals who have a disease with potentially fatal consequences, and the criminalization of the licensed physician who felt it appropriate to prescribe laetrile to those cancer patients. The state sanctioned treatments of surgery, chemotherapy, and radiation therapy involve the presence of physical pain, the creation of anxiety and apprehension of medical or other damage, permanent disfigurement and complications, risk of irreversible injury to health, and danger to life itself. The immediate impact of this decision necessitates acceptance of these risks or turns the matter of treatment back to the patient without any assistance from a licensed physician.

The court below also stated: "The lesson of Roe v. Wade [(1973) 410 U.S. 113] for our case is that a requirement that a drug be certified effective for its intended use is a reasonable means to insure maximum safety for the patient."

The court's reasoning would mean that no legal difference would exist between the terms "safe" and "effective." Roe dealt specifically with choice of medical treatment. This Court made it clear that during the first trimester of pregnancy, when abortion is less hazardous in terms of the woman's life than carrying the child to term would be, the state may require only that the abortion be performed by a licensed physician. No further regulations are compelling justified. After the first trimester, the compelling state interest in the mother's health permits it to adopt reasonable regulations, not a complete ban, in order to promote safe abortions. But requiring abortions to be performed in hospitals or only after approval of another doctor or committee in addition to the woman's physician,

is impermissible.

The broad sweep of the opinion below would mandate state sanctioned treatments or nothing at all for cancer patients too frail for state sanctioned treatments and for cancer patients diagnosed as terminal for whom state sanctioned treatments are useless. For patients too frail for state sanctioned treatments, nutritional treatment that includes laetrile is less hazardous in terms of the patient's life than state sanctioned treatments would be. For patients diagnosed as terminal by competent medical advisors, the terms "safe" and "effective" have no reasonable application. The lesson to be learned from Roe is that at least until the medical treatment sought to be prohibited is more dangerous than the state sanctioned alternatives, the Constitutional right of privacy protects the one seeking treatment and the physician who offers that treatment.

The court below also stated: "Planned Parenthood [(1976) 48 U.S. 52] thus stands for the proposition that although the decision to have an abor-

tion may be within the constitutional zone of privacy deserving the protection provided by the compelling interest standard, the selection of a particular procedure is a medical matter to which privacy status does not attach and which may be regulated by the government, providing a rational basis for such regulation exists."

This ignores that in Planned Parenthood the Court invalidated a state prohibition on the use of saline ammiocentesis as a method of abortion after the first twelve weeks of pregnancy. As in Roe, the "compelling point" was not reached until after the first trimester when the treatment sought to be prohibited approached the point of being more dangerous than the state sanctioned alternatives. Even after reaching the "compelling point, "the Court recognized that saline ammiocentesis was not harmful to the patient and held that the flat prohibition of the substance was a restriction which does not reasonably relate to the preservation and protection of maternal health.

Planned Parenthood contains the lesson from Roe that until the medical treatment sought to be prohibited is more dangerous than the state sanctioned alternatives, the Constitutional right of privacy protects the one seeking treatment and the physician who offers that treatment. The lesson to be learned from Planned Parenthood is that the flat prohibition of a medical treatment administered by a licensed physician that is not harmful to the patient does not reasonably relate to the preservation and protection of the public health. Therefore, the flat prohibition of a medical treatment that is safer for the particular patient than the state sanctioned alternatives certainly cannot be reasonably related to the preservation and protection of the public health.

No right or individual liberty is more fundamental, historic or traditional than the individual medical decision about how to survive. In balancing changing competing social values that revolve around this fundamental right,

the Court has provided clear principles and boundaries to govern unjustified intrusions into the individual decision making process. Until the medical treatment sought to be prohibited is more dangerous than the state sanctioned alternatives, the Constitutional right of privacy and personal liberty protects the one seeking treatment and the physician who offers that treatment. The court's decision below would change those principles and boundaries and allow the state to make this most fundamental decision without consultation with the patient.

2. The protection of the rights of other citizens is involved.

The case is important to Petitioner in that Petitioner will have to serve a term in jail if the writ is not granted. The case is important to individual cancer victims afflicted with a horrible disease who want to make their own decisions concerning the treatment they will pursue in an attempt to preserve their health or save their lives. The case also involves a frightening governmental intrusion into

an area which has been historically recognized as the domain of the individual. It involves the imposition on individuals of highly personal and subjective decisions affecting the most important and intimate aspects of their lives by an impersonal bureaucracy to which they have no access. Decisions are made for individual cancer victims by an inaccessible bureaucracy which controls the context of facts and values in which policies are shaped. Long after the laetrile controversy has been decisively settled within the medical and scientific communities, the legal principles established in this case will have a profound effect on the relationship, and the respective rights, of government and its citizens.

The decision below, as it stands, moves this nation one step closer to the establishment of a society in which the government, under the guise of protecting the ignorant, the gullible and the foolhardy, assumes the right to control knowledge and make decisions concerning the most intimate and personal aspects of the lives

of all of the people. Social and political power is kept from citizens in the form of "knowledge." Decisions are made under standards of "rationality" decreed and applied by large bureaucratic entities to which the people have no meaningful access. The people have been deprived of the right to control their own lives, and have lost the individuality which is the essence of their humanity. Government is given the power to control men's minds. The individual becomes a mere creature of the state and a vehicle for other people's views.

In a Constitutional government that recognizes the right of individuals to enjoy life and liberty and to pursue happiness, this kind of governmental intrusion cannot be tolerated.

3. The decision below raises problems similar to those now pending before the Court regarding the validity and application of Food, Drug and Cosmetic Act Section 505, 21 U.S.C. 355.

United States v. Rutherford, No. 78-605, Oct. Term 1978, which is presently

pending decision before the Court, raises substantially similar problems regarding the Constitutional validity and reasonable application of Section 505. As presently interpreted and applied by the Food and Drug Administration, Section 505 completely bans an informed cancer victim from receiving laetrile, an otherwise harmless but controversial treatment, unless the prior consent of government officials is obtained.

California Health and Safety Code Section 1707.1 adopts substantially similar procedures as contained in Section 505 for obtaining prior consent of state officials. Section 1707.1 specifically incorporates Section 505 as a method of obtaining prior consent of state officials. As interpreted and applied by the court below, Section 1707.1 completely bans an informed consenting cancer patient from receiving laetrile from a licensed physician unless the prior consent of state officials is obtained.

Rutherford does not raise Constitutional problems in terms of facts wholly

identical to those here involved. Petitioner, a licensed medical doctor, stands convicted of a crime for prescribing laetrile which is not narcotic, habit forming, hallucinatory or toxic to knowledgeable persons fully aware of the nature of state sanctioned cancer therapies before seeking treatment from Petitioner.

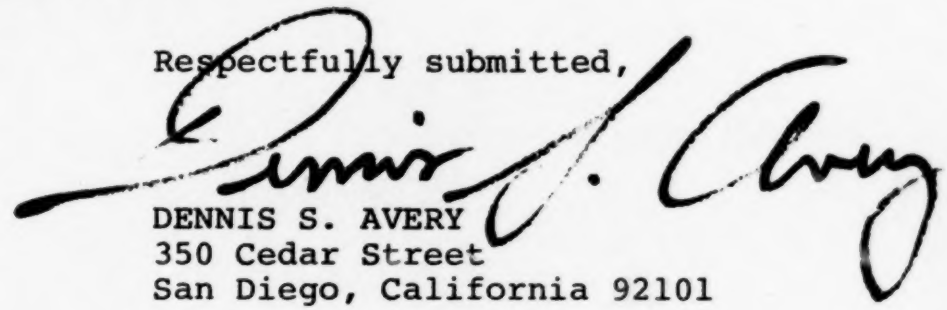
If the Court finds in Rutherford that a total prohibition of the cancer victims informed decision to use and obtain laetrile is an impermissible deprivation of liberty or not reasonably related to the preservation and protection of the public health, this case may be controlled by the Rutherford result.

It would therefore seem appropriate to withhold action on the instant petition until the Rutherford case has been resolved by this Court and to assess the appropriateness of reviewing the Constitutional ruling below in light of the decision in that case.

CONCLUSION

For these reasons, a writ of certiorari should issue to review the judgment and opinion of the California Supreme Court.

Respectfully submitted,



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APPENDIX A

IN THE SUPREME COURT OF
THE STATE OF CALIFORNIA

Crim. 20340

[Filed March 15, 1979]

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiff and Respondent,

v.

JAMES ROBERT PRIVITERA, JR., et al,
Defendants and Appellants

Under California Health and Safety Code section 1707.1, it is a misdemeanor to sell, deliver, prescribe or administer any drug or device to be used in the diagnosis, treatment, alleviation or cure of cancer which has not been approved by the designated federal agency (21 U.S.C. § 355) or by the state board (Health & Saf. Code, § 1704).[1/]

1/ Section 1707.1 provides: "The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine, compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless

(1) an application with respect thereto has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act, or (2) there has been approved an application filed with the board setting forth: [¶] (a) Full reports of investigations which have been made to show whether or not such drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use; [¶] (b) A full list of the articles used as components of such drug, medicine, compound or device; [¶] (c) a full statement of the composition of such drug, medicine, compound or device; (d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug, medicine or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation; [¶] (e) Such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and [¶] (f) Specimens of the labeling and advertising proposed to be used for such drug, medicine, compound or device."

(End of fn. 1.)

Defendants James Robert Privitera, Jr., a medical doctor, William David Turner, Phyllis Blanche Disney, Winifred Agnes Davis, and Carroll Ruth Leslie were convicted by jury of the felony of conspiracy to sell and to prescribe an unapproved drug--laetrile--intended for the alleviation or cure of cancer. (Pen. Code, § 182, subd. 1; Health & Saf. Code, § 1707.1.) Davis and Turner were also convicted of selling laetrile for the alleviation or cure of cancer. (Health & Saf. Code, & 1707.1.)

Viewed in the light most favorable to the judgments (see People v. Reilly (1970) 3 Cal.3d 421, 425), the evidence amply supports the jury's conclusion that defendants were involved in a common plan to import, prescribe, sell and distribute laetrile (also referred to as amygdalin or vitamin B-17) to cancer patients. Dr. Privitera prescribed laetrile for cancer patients and referred his patients to Turner and Disney as suppliers of laetrile. Disney referred patients to Dr. Privitera for treatment. Leslie and Disney worked as distributors in various residential areas. De-

fendants told prospective users that laetrile is an effective treatment or cure for cancer. Laetrile has not been approved for that purpose by one of the designated governmental agencies.

Defendants appeal on the ground that the statute is unconstitutional. They contend the right of privacy protected by the federal and California Constitutions includes a right to obtain laetrile or, more generally, a right of access to drugs not recognized by the government as effective. Fundamental rights, defendants point out, may be regulated only to the extent necessary to achieve a compelling state interest. Defendants argue the purported right to obtain laetrile is fundamental and therefore the regulation challenged here must be reviewed under the compelling state interest standard. Section 1707.1 is found to be unconstitutional, defendants conclude, when measured against that standard.

We hold the asserted right to obtain drugs of unproven efficacy is not encompassed by the right of privacy embodied in either the federal or the state Con-

stitutions. The appropriate standard of review, therefore, is the rational basis test, rather than the compelling state interest test. We conclude section 1707.1 amply satisfies the applicable standard by bearing a reasonable relationship to the achievement of the legitimate state interest in the health and safety of its citizens.

THE UNITED STATES CONSTITUTION

The Supreme Court has held that regulations limiting certain fundamental rights may be justified only by a compelling state interest (Kramer v. Union Free School District (1969) 395 U.S. 621, 627; Shapiro v. Thompson (1969) 394 U.S. 618, 634; Sherbert v. Verner (1963) 374 U.S. 398 406), and that legislative enactments must be narrowly drawn to express only the legitimate state interest at stake (Griswold v. Connecticut (1965) 381 U.S. 479, 485; Aptheker v. Secretary of State (1964) 378 U.S. 500, 508; Cantwell v. Connecticut (1940) 310 U.S. 296, 307-308). The right of privacy, founded in the Fourteenth Amendment's concept of personal

liberty and restriction upon state action, has been declared a fundamental right. (Roe v. Wade (1973) 410 U.S. 113, 152-155.) Thus, if the right of privacy were implicated in this case the challenged statute would, arguably, be judged under the compelling state interest standard.[2/]

However, a fundamental privacy right is not at stake here. The interest defendants allege is, apparently, "the interest in independence in making certain kinds of important decisions." (Whalen v. Roe (1977) 429 U.S. 589, 599-600.) But the kinds of "important decisions" recognized by the high court to date as falling within the right of privacy involve "matters relating to marriage, procreation, contraception, family relationships, and child

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2/ However, as we shall see, even statutes restricting exercise of a right found by the United States Supreme Court to be a fundamental privacy right are reviewed under the rational basis standard when the danger to health is significant. (Roe v. Wade, supra, 410 U.S. 113, 163.)

rearing and education'" (Whalen v. Roe, supra, 429 U.S. at p. 600, fn. 26, quoting Paul v. Davis (1976) 424 U.S. 693, 713), but do not include medical treatment.

For this reason defendants' reliance on Roe v. Wade, supra, 410 U.S. 113, is misplaced. In that case a majority of the high court held the decision to have an abortion falls within the right of privacy, a conclusion following from the court's earlier decisions that activities relating to procreation (Skinner v. Oklahoma (1942) 316 U.S. 535, 541-542) and contraception (Eisenstadt v. Baird (1972) 405 U.S. 438, 453-454) were also protected by that right. (410 U.S. at pp. 152-153.) However, emphasizing that this privacy right is not absolute, the court stated: "The Court's decisions recognizing a right of privacy also acknowledge that some state regulation in areas protected by that right is appropriate. As noted above, a State may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life . . . . The privacy

right involved, therefore, cannot be said to be absolute." (410 U.S. at pp. 153-154.)

Significantly, when danger to health exists Roe v. Wade indicates that state regulation shall be tested under the rational basis standard. (410 U.S. at p. 163.) Indeed, the high court held in Roe v. Wade that a state may--without encroaching upon any right of privacy--further its important interest "in the areas of health and safety" by requiring abortions be performed at licensed institutions which "insure maximum safety for the patient" and prohibiting performance of abortion by a person not a physician as defined by state law. (410 U.S. at pp. 149, 150, 163-165.) The lesson of Roe v. Wade for our case is that a requirement that a drug be certified effective for its intended use is a reasonable means to "insure maximum safety for the patient."

In Planned Parenthood of Central Missouri v. Danforth (1976) 428 U.S. 52, the high court struck down a state prohibition of a particular abortion pro-

cedure on the ground the prohibition did not reasonably relate to preservation and protection of maternal health. Significantly, in discussing the validity of the statutory prohibition of the medical procedure, the court did not refer to any constitutional considerations of privacy. Rather the procedure was evaluated by the court on the basis of medical evidence of its safety and effectiveness under the rational basis standard. Planned Parenthood thus stands for the proposition that although the decision to have an abortion may be within the constitutional zone of privacy deserving the protection provided by the compelling interest standard, the selection of a particular procedure is a medical matter to which privacy status does not attach and which may be regulated by the government, providing a rational basis for such regulation exists.

Whalen v. Roe, supra, 429 U.S. 589 provides additional support for our conclusion that the appropriate standard for reviewing section 1707.1 is the rational basis test. In Whalen v. Roe

the high court upheld a New York statute requiring that the patient's name, address and age--among other information--be filed with the state department of health whenever a "Schedule II" drug is prescribed.3/ Finding the state "had been unable to demonstrate the necessity for the patient-identification requirement on the basis of its experience during the first 20 months of administration of the new statute," the district court held that "the doctor-patient relationship is one of the zones of privacy accorded constitutional protection' and that the patient-identification provisions of the Act invaded this zone with a 'a needlessly broad sweep.'" (429 U.S. at

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3/ The New York statute classified potentially harmful drugs in five schedules. Drugs, such as heroin, which are highly abused and have no recognized medical use, are in schedule 1. Schedules II through V include drugs which have a progressively lower potential for abuse but also have a recognized medical use. Schedule II includes the most dangerous of the legitimate drugs. (Id. at pp. 592-593.)

p. 596.) Rejecting the standard employed by the district court, the high court reaffirmed that "State legislation which has some effect on individual liberty or privacy may not be held unconstitutional simply because a court finds it unnecessary, in whole or in part. For we have frequently recognized that individual States have broad latitude in experimenting with possible solutions to problems of vital local concern." (Id. at p. 597, fns. omitted.)

Although recognizing that, "[u]nquestionably, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention" (id. at p. 602), the Supreme Court upheld the patient-identification requirement under the rational basis test. "The New York statute challenged in this case represents a considered attempt to deal with [a problem of vital local concern]. It is manifestly the product of an orderly and rational legislative decision . . . . There surely was nothing unreasonable in the assumption that the patient-identification require-

ment might aid in the enforcement of laws designed to minimize the misuse of dangerous drugs. For the requirement could reasonably be expected to have a deterrent effect on potential violators as well as to aid in the detection or investigation of specific instances of apparent abuse. At the very least, it would seem clear that the State's vital interest in controlling the distribution of dangerous drugs would support a decision to experiment with new techniques for control. For if an experiment fails--if in this case experience teaches that the patient-identification requirement results in the foolish expenditure of funds to acquire a mountain of useless information--the legislative process remains available to terminate the unwise experiment. It follows that the legislature's enactment of the patient-identification requirement was a reasonable exercise of New York's broad police powers." (Id. at pp. 597-598.)

Finally, the high court reiterated: "It is, of course, well settled that the

State has broad police powers in regulating the administration of drugs by the health professions. Robinson v. California, 370 U.S. [660], at 664-665; Minnesota ex rel. Whipple v. Martinson, 256 U.S. [41], at 45; Barsky v. Board of Regents, 347 U.S. 442, 449." (Whalen v. Roe, supra, at p. 603, fn. 30.) Although it had not done so, the court observed, "the State no doubt could prohibit entirely the use of particular Schedule II drugs." (Id. at p. 603.) If the state has the power to ban a drug with a recognized medical use because of its potential for abuse, then--given a rational basis for doing so--the state clearly has the power to ban a drug not recognized as effective for its intended use.

The legitimate state interest expressed in the challenged statute is set forth in the legislative findings recited in section 1700. "The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicate that approximately 16 percent of

the deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom. [¶] Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various persons in this State have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment or cure of cancer, which representations are misleading to the public, with the result that large numbers of the public, relying on such representations, needlessly die of cancer, and substantial amounts of the

savings of individuals and families relying on such representations are needlessly wasted." (Health & Saf. Code, § 1700.)

These findings were recently echoed by the Commissioner of the federal Food and Drug Administration with specific reference to laetrile. "In the Commissioner's opinion, the use of Laetrile in the United States has become a genuine public health problem. Increasingly, doctors dealing with cancer patients are finding that the patients are coming to legitimate therapy too late, having delayed while trying Laetrile. It seems clear that another substantial group of persons afflicted with cancer is avoiding effective therapy altogether and using Laetrile instead. The question has become one of life and death for these patients and for others who may be convinced to use Laetrile in the future." (42 Fed.Reg. 39769.)

The commissioner rendered his opinion at the conclusion of a rulemaking proceeding undertaken in compliance with the opinion of the court of appeals in

Rutherford v. United States (10th Cir. 1976) 542 F.2d 1137, and the order of the district court in Rutherford v. United States (W.D.Okla. 1977) 424 F.Supp. 105. "Based upon a careful review of the administrative record," the commissioner found that "Laetrile is not generally recognized by qualified experts as a safe and effective cancer drug." (42 Fed.Reg. 39775.) The commissioner further found laetrile does not qualify for exemption from the new drug provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) by virtue of compliance with the 1962 grandfather clause of the act. (42 Fed. Reg. 39795.) Distribution of laetrile in interstate commerce, the commissioner concluded, is thus illegal and subject to regulatory activity by the Food and Drug Administration.

Because of defendants' reliance on it, subsequent developments in the Rutherford case will now be considered. In Rutherford v. United States (W.D.Okla. 1977) 438 F.Supp. 1287, the district court set aside the commissioner's action

and enjoined federal authorities from interfering with distribution of laetrile in interstate commerce or with use of laetrile for the treatment of cancer. The decision was based on two grounds: First, contrary to the conclusion reached by the commissioner, the court held that laetrile is exempt from the premarket approval requirement for new drugs by virtue of compliance with the 1962 grandfather clause. (438 F. Supp. at pp. 1294-1298.) Second, contrary to the conclusion we reach today, the court concluded the federal right of privacy encompasses a "right to use a nontoxic substance in connection with one's own personal health-care." (Id. at p. 1301.)

On appeal by the government, the court of appeals addressed neither the grandfather clause question nor the right of privacy issue. Instead, the court held that "the 'safety' and 'effectiveness' terms used in the statute have no reasonable application to terminally ill cancer patients." "We are considering only cancer patients who are terminally

ill and only their intravenous use of Laetrile. Thus in this context, what can 'generally recognized' as 'safe' and 'effective' mean as to such persons who are so fatally stricken with a disease for which there is no known cure? What meaning can 'effective' have in the absence of anything which may be used as a standard? Under this record Laetrile is as effective as anything else. What can 'effective' mean if the person, by all prevailing standards. . . is going to die of cancer regardless of what may be done." The permanent injunction granted by the district court was continued but limited only to permit procurement of intravenous injections of laetrile administered by a licensed medical practitioner to persons who are certified by a licensed medical practitioner to be terminally ill of cancer in some form. (Rutherford v. United States (10th Cir. 1978) __F.2d__ (No. 77-2049; filed 10 July 1978).)[4/]

4/ On 22 January 1979 certiorari was granted in Rutherford. (47 U.S.L.Week 3492, Dock. No. 78-605.)

Defendants can take no comfort in the court of appeals' decision for, unlike Rutherford, this case is not an action on behalf of the class of terminally ill cancer patients. Whatever may be said in favor of permitting "terminal" cancer patients access to laetrile, there is no indication in the record that defendants sought to restrict their activities to that class when prescribing, distributing and administering laetrile. Indeed, the record reflects that Dr. Privitera sometimes neither took a medical history from nor personally examined the patients for whom he prescribed laetrile. The lay defendants, of course, were not qualified to diagnose cancer, much less to determine whether a cancerous condition was "terminal."

Moreover, we are not prepared to reject as unreasonable the explanation given by the commissioner for the Food and Drug Administration's refusal to approve laetrile for use by "terminal" cancer patients.[5/] The commissioner

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5/ The court of appeals did not mention or discuss the reasons given by the commissioner.

concluded: "[A]pproval of Laetrile restricted to 'terminal' patients would lead to needless deaths and suffering among (1) patients characterized as 'terminal' who could actually be helped by legitimate therapy and (2) patients clearly susceptible to the benefits of legitimate therapy who would be misled as to Laetrile's utility by the limited approval program or who would be able to obtain the drug through inevitable leakage in any system set up to administer such a program." (42 Fed.Reg. 39805.) Substantial evidence in the administrative record appears to support the conclusion reached by the commissioner.6/ Certainly the record in

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6/ For example, with regard to the impossibility of determining "who is terminal," the commissioner cited Dr. Peter H. Wiernik, Chief of the Clinical Oncology Branch of the National Cancer Institute's Baltimore Cancer Research Center, who stated "One major difficulty in making a particular chemical available for terminal patients only is that no one can prospectively define the term 'terminal' with any accuracy. A patient can be said to be terminal only after he dies. Many patients who are critically ill respond to modern day management of cancer." This opinion was shared by

(Fn. 6 continued.)

this case does not inspire one with confidence that advocates of laetrile would cooperate with a regulation restricting it to "terminal" cancer patients. In studied defiance of current law, Dr. Privitera prescribed and administered the drug as a cancer cure, advised his patients to discontinue conventional treatment, and warned them not to let their regular physicians know they were taking laetrile.

In conclusion, we emphasize we are not taking sides on the fiercely contested medical questions regarding laetrile's safety or efficacy as a cancer drug. Laetrile advocates may yet be vindicated in the court of scientific opin-

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Dr. Joseph F. Ross, Professor of Medicine at the University of California School of Medicine at Los Angeles. Dr. Ross stated "[T]he distinction of 'terminal' patients from 'non-terminal' may not be reliably determined and an assumption that Laetrile may be given to such patients with impunity may deprive such patients of therapeutic measures which could help them." As Helen Brown, Executive Director of Cancer Control/Los Angeles, put it, "No one knows if and when any patient is going to die." (42 Fed.Reg. 39805.)

ion, for even as this is being written the National Cancer Institute is seeking approval from the Food and Drug Administration to test laetrile on advanced cancer patients. (Cancer Institute Seeks to Test Laetrile, L.A. Times (28 Sept. 1978) pt. I, p. 14, cols. 1-6.) Nor are we endorsing the decision the Legislature has made on the basis of existing scientific evidence. Whether cancer patients--especially advanced cancer patients who have unsuccessfully sought relief from conventional therapy and who are fully informed as to the consensus of scientific opinion concerning the drug--should have access to laetrile is clearly a question about which reasonable persons may differ. It is not our function to render scientific or legislative judgments. Rather, we must resolve a narrow question: Does the challenged legislation bear a reasonable relationship to the achievement of the legitimate state interest in the health and safety of its citizens? We conclude section 1707.1 does satisfy this

standard and that it therefore does not encroach upon the federal constitutional right of privacy.

THE STATE CONSTITUTION

Having determined the federal constitutional right of privacy does not encompass a right of access to drugs of unproven efficacy, we next determine whether the voters of California intended to create such a right in November 1972 when they amended article I, section 1 of our Constitution to include among the various "inalienable" rights of "all people" the right of "privacy."7/

7/ Article I, section 1 (as reworded by constitutional amendment in Nov. 1974) now reads: "All people are by nature free and independent, and have certain inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing, and protecting property, and pursuing and obtaining safety, happiness, and privacy."

There is simply no evidence of such intent. To the contrary, in White v. Davis (1975) 13 Cal.3d 757, we observed "the moving force behind the new constitutional provision was a more focussed privacy concern, relating to the accelerating encroachment on personal freedom and security caused by increased surveillance and data collection activity in contemporary society. The new provision's primary purpose is to afford individuals some measure of protection against this most modern threat to personal privacy." (Id. at p. 774.) As we further observed, "[t]he principal objectives of the newly adopted provision are set out in a statement drafted by the proponents of the provision and included in the state's election brochure," the beginning paragraphs of which we then quoted: "'The proliferation of government snooping and data collecting is threatening to destroy our traditional freedoms. Government agencies seem to be competing to compile the most extensive sets of dossiers of American citizens. Computerization of

records makes it possible to create "cradle-to-grave" profiles of every American. [¶] At present there are no effective restraints on the information activities of government and business. This amendment creates a legal and enforceable right of privacy for every Californian.' (Italics in the original.)" (13 Cal.3d at p. 774.)

The election brochure argument by the proponents of the provision "represents, in essence, the only 'legislative history' of the constitutional amendment available to us." (Id. at p. 775.) In the absence of any evidence that the voters in amending the California Constitution to create a right of privacy intended to protect conduct of the sort engaged in by defendants, we have no hesitation in holding that section 1707.1 does not offend that constitutional provision.

FAILURE TO PRESERVE SEARCH AND SEIZURE ISSUE

Defendants finally contend that the trial court erred in denying their motion to suppress certain evidence ob-

tained on execution of a telephonic search warrant.

Subdivision (b) of section 1528 of the Penal Code provides in pertinent part that a magistrate may orally authorize a peace officer to sign the magistrate's name on a duplicate original search warrant. Defendants argue that attempted action under this provision failed here because the person authorized to sign the magistrate's name--a federal customs service special agent--was not a "peace officer" under California law.

The People correctly respond that defendants are precluded from raising this issue by their failure to preserve it by appropriate objection below. "[T]he general rule [is] that questions relating to the admissibility of evidence will not be reviewed on appeal in the absence of a specific and timely objection in the trial court on the ground sought to be urged on appeal. (See Evid. Code, § 353; People v. Welch (1972) 8 Cal.3d 106, 114-115; People v. De Santiago (1969) 71 Cal.2d

18, 22.) The contrary rule would deprive the People of the opportunity to cure the defect at trial and would 'permit the defendant to gamble on an acquittal at his trial secure in the knowledge that a conviction would be reversed on appeal.' (Coy v. Superior Court (1959) 51 Cal.2d 471, 473.)" (People v. Rogers (1978) 21 Cal.3d 542, 548.)

The reason for the rule is well illustrated here. While conceding a federal customs agent is not, per se, a "peace officer" under California law (see Pen. Code, § 7, subd. 8, and § 830 et seq.), the People suggest Agent Nadel may nevertheless have acquired such status by process of cross-deputization. As the issue was not raised below, the People had no occasion to pursue the point and, therefore, defendants may not raise it now.

We have considered defendants' remaining contentions and find them to lack merit.

The judgments of conviction are affirmed.

CLARK, J.

WE CONCUR:

TOBRINER, J.
MOSK, J.
RICHARDSON, J.
MANUEL, J.

DISSENTING OPINION BY BIRD, C.J.

I respectfully dissent.

I do not question for a moment that the effective treatment of persons suffering from cancer is a matter of paramount public importance. However, we are dealing here with a disease whose causes and treatment continue to baffle the medical community. Among physicians and scientists themselves there remains legitimate dispute as to what is truly an effective program of treatment for cancer. So long as there is no clear evidence that laetrile is unsafe to the user, I believe each individual patient has a right to obtain the substance from a licensed physician who feels it appropriate to prescribe it to him.

Cancer is a disease with potentially fatal consequences; this makes the choice of treatment one of the more important decisions a person may ever make, touching intimately on his or her

being. For this reason, I believe the right to privacy, recognized under both the state and federal Constitutions, prevents the state from interfering with a person's choice of treatment on the sole grounds that the person has chosen a treatment which the state considers "ineffective."

The right of privacy is a concept of as yet undetermined parameters. Justice Staniforth's opinion for the Court of Appeal in this case provides as decent a map through this difficult terrain as I believe is available. For this reason, I herewith reprint his opinion.*

"Under California Health and Safety Code section 1707.1,[1/] it is a misdemeanor to sell, deliver, prescribe or administer any drug or device to be

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1/ Health and Safety Code section 1707.1 provides:

"The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine,

(Fn. continued)

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* See page 2a for comment.

(Fn. 1 continued)

compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act [21 USCS § 355], or (2) there has been approved an application filed with the board setting forth:

"(a) Full reports of investigations which have been made to show whether or not such drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use;

"(b) A full list of the articles used as components of such drug, medicine, compound or device;

"(c) A full statement of the composition of such drug, medicine, compound or device;

"(d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of

* Since Justice Staniforth wrote the opinion which I am setting forth here, the case of Rutherford v. United States has continued its way through the courts. In 1977 the Federal Drug Administration held administrative proceedings and determined that laetrile was a "new drug," and that it should not receive agency approval, since the drug was not proven "safe and effective" in the treatment of cancer. The case then returned to federal district court, where the judge set aside the Federal Drug Administration determination and enjoined the agency from interfering with the use of laetrile by terminally ill cancer patients. (Rutherford v. United States (W.D. Okla. 1977) 438 F. Supp. 1287, 1301.) On appeal, the Tenth Circuit Court of Appeals affirmed. The court noted: "We are considering only cancer patients who are terminally ill . . . . [I]n this context, what can 'generally recognized' as 'safe and effective' mean as to such persons who are so fatally stricken with a disease for which there is no known cure? What meaning can 'effective' have in the absence of anything which may be used as a standard?" (Rutherford v. United States (10th Cir. 1978) ___ F.2d ___.) On Monday, January 22, 1979, the United States Supreme Court agreed to hear the Rutherford case. (See Los Angeles Times, Monday, January 22, 1979, p. 1.)

used in the diagnosis, treatment, alleviation or cure of cancer which has not been approved by the designated federal agency (21 U.S.C.S. § 355) or by a state board (Health & Saf. Code, § 1704).

Defendants, James Robert Privitera, Jr., a medical doctor, William David Turner, Phyllis Blanche Disney, Winifred Agnes Davis, and Carroll Ruth Leslie, were convicted by jury of a felony, conspiracy to sell, to prescribe, an unapproved drug, laetrile, intended for the alleviation or cure of cancer. (Pen.

(Fn. 1 continued)

such drug, medicine or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation;

"(e) Such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and

"(f) Specimens of the labeling and asvertising proposed to be used for such drug, medicine, compound or device."

Code, § 182, subd. 1; Health & Saf. Code, § 1707.1.) Davis and Turner were convicted of selling laetrile to be used for the alleviation or cure of cancer (Health & Saf. Code, § 1707.1.)

We view the evidence in the light most favorable to the judgments. (People v. Reilly, 3 Cal.3d 421, 425 [90 Cal.Rptr. 417, 475 P.2d 649].) The defendants were involved in a common plan to import, distribute and prescribe laetrile (also referred to as amygdalin or vitamin B-17) to cancer patients. Defendants Turner and Davis were importers and chief suppliers of the drug. Defendants Leslie and Disney worked as the distribution network in various residential areas. Dr. Privitera prescribed amygdalin for cancer victims (or to undercover state agents represented to be cancer victims). Dr. Privitera referred patients to Turner and Davis to buy the amygdalin; Disney referred patients to Dr. Privitera for treatment.

The defendants told the prospective users of the drug that amygdalin was an effective treatment or cure for cancer.

Substantial evidence supports the jury finding of a common plan or agreement to supply and prescribe amygdalin as a cancer cure. Laetrile has not been "approved" by a designated governmental agency.

I

Contentions of the Parties -- Factual and Legal

Dr. Privitera contends that California Health and Safety Code section 1707.1 is an unconstitutional invasion of the cancer victim's right to obtain and use amygdalin in violation of rights guaranteed by the United States Constitution, Amendments I, IV, V, VI, VII, VIII, and XIV, and California Constitution, article I, sections 1, 7, 7(a) and 15. This, he asserts, is an invasion of the patient's right of privacy, his or her right to be left alone in choice of orthodox versus unorthodox treatment of cancer. As a corollary and necessary concommitant of the right of privacy of the patient, Dr. Privitera argues that the constitutional protec-

tion accorded the cancer victim's right to utilize amygdalin in a program of nutritional therapy extends to physicians willing to administer the drug and to persons willing to supply the drug for the cancer victim's use. Argues Dr. Privitera: "The protection of constitutional guarantees of privacy and personal liberty, therefore, extends not only to the patient pursuing a course of nutritional therapy but to the physician who prescribes and administers the therapy and to the person who furnishes the essential components."

Dr. Privitera does not challenge the validity of the general or specific regulatory laws to the extent they prohibit the advertisement of amygdalin as a cure for cancer (Health & Saf. Code, § 1714); or require amygdalin be labeled in accordance with state law and regulations (Health & Saf. Code, § 26463); or impose standards on the manufacturing and packing of amygdalin to insure quality and prevent adulteration or deterioration, or the prohibition of the sale of amygdalin to members of the

general public for the purpose of treating cancer by persons other than licensed physicians (Health & Saf. Code, § 26400 et seq.). (Health & Saf. Code, §§ 1704, 26670, 1707.1, 1709; 17 Cal. Admin. Code, § 10400.1.)

Rather, Dr. Privitera's challenge is directed to those laws, specifically the one of which he is convicted, insofar as they prohibit a duly licensed physician from administering amygdalin to cancer patients and which prohibit its sale to either licensed physicians or persons who have obtained prescriptions from a licensed physician. (Health & Saf. Code, §§ 1700-1721.)

According to Dr. Privitera, this right of choice of medical treatment is a fundamental right of the individual and regulations limiting this right may be justified only by "compelling state interests"; the legislative enactments which seek to regulate or control in the areas of such fundamental rights must be narrowly drawn to protect only the legitimate state interests at stake.

The specific drug here supplied or prescribed is a substance known as

amygdalin, also known as laetrile, and also known as vitamin B-17. Amygdalin is a by-product of apricot pits. The substance has been the subject of widespread public dispute as to its efficacy for the treatment of cancer. Orthodox medicine, as represented by the American Cancer Society, places it in the area of nostrums. Its proponents vary in their claims from that as a cure for cancer or as simply a nutritional aid causing the patient to gain weight, have a better appetite, and a better emotional outlook. It is generally conceded that amygdalin is nontoxic; it does not fall within the general ban of drugs which are toxic, habit forming, addictive, or otherwise distort reality. Coventional medicine regards the "evidence," "proof," of the curative effect of amygdalin as anecdotal in nature and contends the drug has never been established by scientific methodology to have any effect whatsoever upon either the cure or retardation of cancer growth. Despite the pros and cons of the experts in the field of

medicine, and others from nonmedical fields taking side on this issue, cancer victims in large numbers have sought the relief, whatever its nature, which is available from the use of this drug. Where, as in Mexico and in West Germany, the drug is available through doctors and clinics, cancer victims, able to travel, seek out and obtain the treatment.

Dr. Privitera points out that many cancer victims have investigated and evaluated the merits of surgery, radiation therapy or chemotherapy with the aid of competent medical advice and have made the highly personal decision [that] the benefits from such therapy [are] not sufficient to justify the risks which include disfigurement, debilitation, and accelerated death and for this reason have chosen to seek amygdalin as a treatment; other cancer victims have been advised that their condition is hopeless, their case is terminal and as a last resort before certain death, seek amygdalin.

Dr. Privitera contends many concerned cancer victims, competent and responsible

adults, seek and use amygdalin as a food substance to ameliorate the horrifying physical wasting away of the body (cachexia) which accompanies cancer. Thus they seek amygdalin not only for its possible cancer curative benefits, but also for its known nutritional benefits. Cancer victims cannot be certain amygdalin will either cure or control cancer but they believe, based upon the anecdotal, personal experience approach, the drug provides relief from the terrible pain, mental malaise, the emotional depression and weight loss which mark the progression of their disease.

The People assert, contrary to Dr. Privitera's contentions, not a single accredited medical school in the State of California teaches amygdalin might be effective in the controlling or curing of cancer. Further the use of amygdalin as a form of nutritional therapy is officially regarded by the State Department of Health, the California Medical Association, the National Cancer Institute and a great block of practicing physicians, to be of no value

whatsoever in the controlling or curing of cancer.

Dr. Privitera specifically contends section 1707.1 of the Health and Safety Code is unconstitutional. It is a denial of one aspect of individual "liberty" protected by the due process of the Fourteenth Amendment.

The patient, he asserts, has a right of "privacy" or "a guarantee of certain areas or zones of privacy." This is the individual right of independence in making certain kinds of important decisions. The very nature of the relationship, the act to be performed, the decision to be made, precludes unjustified state presence. It is "the right of the individual to be free in action, thought, experience and belief from governmental compulsion." (Kurland, The Private I, University of Chicago Magazine 7, 8, Autumn 1976.) It is that right voiced by Justice Brandeis in his dissent in Olmstead v. United States, 277 U.S. 438, 478 [72 L.Ed. 944, 956, 48 S.Ct. 564, 572, 66 A.L.R. 376] "the right to be let alone", "the right most

valued by civilized men."

Historically this right of privacy was first articulated as a constitutional right in Griswold v. Connecticut, 381 U.S. 479 [14 L.Ed.2d 510, 85 S.Ct. 1678], a decision holding unconstitutional a statute prohibiting the use of contraceptives. However, the recognition of the existence, innate in every human being, of a zone of privacy is older than the Bill of Rights, older than our political parties, older that the state's concern with the nature of treatment to be received by cancer-ridden patients. It is in the nature of man that such right exists.

This principle, now of constitutional dimension, has been embraced by many decisions in a variety of situations.2/

2/ In Morris L. Ernst's and Alan U. Schwartz's Privacy: The Right To Be Left Alone (The Mac Millan Co. 1963), the history and broad sweep of this doctrine is documented. Samuel D. Warren and Louis D. Brandeis, in The Right to Privacy (1890), 4 Harvard Law Review 193, state: " . . . it has been found necessary from time to time to define anew the exact nature and extent of such protection."

(See In re Lifschutz, 2 Cal.3d 415, 432, fn. 12 [85 Cal.Rptr. 829, 467 P.2d 557, 44 A.L.R.3d 1], and Roe v. Wade, 410 U.S. 113, 151-153 [35 L.Ed.2d 147, 175-177, 93 S.Ct. 705, 726].) This concept, when placed in the doctor-patient relationship is the "right to decide independently, with the advice of his physician, to acquire and to use needed medication." (Whalen v. Roe, 429 U.S. 589, 603 [51 L.Ed.2d 64, 75, 97 S.Ct. 869, 876, 878]; Doe v. Bolton, 410 U.S. 179, 197 [35 L.Ed.2d 201, 215-216, 93 S.Ct. 739, 750].) In re Lifschutz, supra, 2 Cal.3d 415, 431, 432, makes this profound insight concerning Griswold: "Indeed, the decision's concern for valued aspects of individual privacy may ultimately aid in protecting man from the dehumanization of an everencroaching technological environment."

The People concede, as they must, the fact, the existence of this expanding and as yet judicially unmeasured concept of individual privacy. However, they contend the State of California has the broad power to establish and enforce

standards of conduct within its borders ralative to health. This is a vital aspect of its police power. Within its ambit is the authority of the state to regulate the delivery of health services. (Barsky v. Board of Regents, 347 U.S. 442, 449 [98 L.Ed. 829, 74 S.Ct. 650, 654]; People v. Nunn, 46 Cal.2d 460, 469 [296 P.2d 813].)

This broad premise authorizes the invasion of the doctor-patient zone of privacy by the state to prohibit the doctor prescribing certain species of drugs. (Blinder v. Division of Narcotic Enforcement, 25 Cal.App.3d 174 [101 Cal.Rptr. 635].) The People point to Whalen v. Roe, supra, 429 U.S. 589, 603, fn. 30 [51 L.Ed.2d 64, 75, 97 S.Ct. 869, 878], and Paris Adult Theatre I v. Slaton, 413 U.S. 49, 65, 67 [37 L.Ed.2d 446, 461-463, 93 S.Ct. 2628], in support of this broad position.

The People concede any exercise of police power, depends in the first instance upon an articulated public interest in the activity to be regulated and second, the means used must be rea-

sonably necessary for the accomplishment of that public purpose. (Goldblatt v. Hempstead, 369 U.S. 590, 594, 595 [8 L.Ed.2d 130, 133-135, 82 S.Ct. 987,990].)

At the heart of the People's defense of Health and Safety Code section 1707.1 is the premise, Legislature declared,[3/] that

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3/ Health and Safety Code section 1700 provides:

"The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicates that approximately 16 percent of the total deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom.

"Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various persons in this State have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, which representations are

(Fn. 3 continued.)

early and accurate diagnosis of cancer materially reduces the likelihood of death, prolongs useful life; where false or misleading representations are made to the public, large numbers rely upon

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(Fn. 3 continued.)

misleading to the public, with the result that large numbers of the public, relying on such representations, needlessly die of cancer, and substantial amounts of the savings of individuals and families relying on such representations are needlessly wasted.

"It is, therefore, in the public interest that the public be afforded full and accurate knowledge as to the facilities and methods for the diagnosis, treatment, and cure of cancer available in this State and that to that end there be provided means for testing and investigating the value or lack thereof of alleged cancer remedies, devices, drugs, or compounds, and informing the public of the facts found, and protecting the public from misrepresentation in such matters.

"The importance of continuing scientific research to determine the cause or cure of cancer is recognized, and the department shall administer this chapter with due regard for the importance of bona fide scientific research and the clinical testing in hospitals, clinics, or similar institutions of new drugs or compounds."

such falsities, and needlessly die of cancer.

The People contend the California Legislature in enacting the statutory scheme made this implicit finding: Ineffective cancer remedies are more hazardous to the patient than the state sanctioned alternatives. (Health & Saf. Code, § 1700.)

Concerning the efficacy of amygdalin, this court, this opinion, does not enter that fray. The effectiveness of amygdalin as a cure for cancer or as a nutritional aid with general health giving benefits, is not, as a matter of law, an issue when the charge is a violation of Health and Safety Code section 1707.1. The issue here is human liberty. Can the informed cancer-ridden patient be limited in choice of treatment received from a state licensed physician to "state sanctioned alternatives"?[4/] To resolve these contra-poised contentions we must carefully analyze the nature of the right protected.

4/ People v. Privitera, 55 Cal.App.3d Supp. 39 [128 Cal.Rptr. 151].

II

The Patient's Right to Privacy

The challenge of Dr. Privitera to Health and Safety Code section 1707.1 resolves itself, upon analysis, into two separate and distinct areas of claimed constitutional rights; there is the right of privacy of the patient to choose or reject his or her own treatment, orthodox or unorthodox, approved or unapproved by the state. The second contention is bifaceted: Dr. Privitera asserts (1) a derivative right -- equal in stature to that of his patient, and (2) the doctor's independent right to practice medicine generally and to prescribe medicine, use procedures, without unreasonable government restrictions.

We examine first the right of the patient and determine this right is of such fundamental nature its free exercise may be impinged upon or forbidden only by such state interest as may be a "compelling interest."

The "fundamental" nature of this right derives from its source. It flows from

the very nature of man. Justice Brandeis in Olmstead v. United States, supra, 277 U.S. 438, 478 [72 L.Ed. 944, 956, 48 S.Ct. 564, 572], stated: "The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone -- the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation . . . ." (Italics added.)

Judge Cardozo in Schloendorff v. Society of New York Hospital, 211 N.Y. 125 [105 N.E. 92, at page 93] stated: "Every human being of adult years and

sound mind has a right to determine what shall be done with his own body; . . . ."

The right to control one's own body is not restricted to the wise; it includes the "foolish" refusal of medical treatment. Nor is this right limited in its recognition to any single segment of the political, economic, or social thought spectrum. In commenting upon Justice Brandeis' most valued of rights, that right to be left alone, now Chief Justice Burger, in his dissent in Application of President & Directors of Georgetown Col. 331 F.2d 1010, at page 1017, stated: "Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to sensible beliefs, valid thoughts, reasonable emotions, or well-founded sensations. I suggest he intended to include a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk."

Without specific reference to a constitutional basis, the right to choose what

may be a suicidal medical course has been upheld. In Erickson v. Dilgard, 44 Misc. 2d 27 [252 N.Y.S.2d 705, 706] a New York court sustained the unwilling Jehovah's Witness' objection to a needed blood transfusion despite risk of death. The court there said at page 706: ". . . it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."

For analogy we look to the very heart of this right of choice of medical procedures, the right to beget or not to beget a child. In the case of Griswold v. Connecticut, supra, 381 U.S. 479 the Supreme Court held unconstitutional a Connecticut statute prohibiting the use of contraceptives. Following Griswold a series of United States Supreme Court cases have attempted to ascertain the boundaries of this aspect of privacy. The outer limits have not yet been determined. However, it is made clear by

decision that unjustified government interference with personal decisions ". . . relating to marriage, Loving v. Virginia, 388 U.S. 1, 12 (1967); procreation, Skinner v. Oklahoma, 316 U.S. 535, 541-542 (1942); contraception, Eisenstadt v. Baird, 405 U.S. at 453-454 id., at 460, 463-465 (White, J., concurring in result); family relationships, Prince v. Massachusetts, 321 U.S. 158, 166 (1944); and child rearing and education, Pierce v. Society of Sisters, 268 U.S. 510, 535 (1925), Meyer v. Nebraska, supra" (Roe v. Wade, supra, 410 U.S. 113, 152-153 [35 L.Ed.2d 147, 177, 93 S.Ct. 705, 726]) violate this concept.

Roe v. Wade, supra, 410 U.S. 113 dealt specifically with the rights to determine one's own medical treatment. The United States Supreme Court held that the mother's constitutional right of privacy was broad enough to encompass her decision whether to terminate her pregnancy before the end of the first trimester of pregnancy. Said the court at page 163 [35 L.Ed.2d at p. 182]: "With respect

to the State's important and legitimate interest in the health of the mother the 'compelling' point, in light of present medical knowledge, is at approximately the end of the first trimester." (Roe v. Wade, supra, 410 U.S. 113, 163 [35 L.Ed. 2d 147, 182, 93 S.Ct. 705, 731].)

In the companion case, Doe v. Bolton, supra, 410 U.S. 179 the United States Supreme Court held the statutes requiring abortions to be conducted in hospitals, or accredited hospitals, requiring the interposition of a hospital abortion committee and thus limiting abortions to those circumstances was unconstitutional. In vindicating the woman's right of choice of medical care, the Supreme Court stated: "The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." (Doe v. Bolton, supra, 410 U.S. 179, 197 [35 L.Ed.2d 201, 216, 93 S.Ct. 739, 750].)

To support its conclusion, the Supreme

Court examined the role of the licensed physician, saying: "If a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice. The attending physician will know when a consultation is advisable -- the doubtful situation, the need for assurance when the medical decision is a delicate one, and the like. Physicians have followed this routine historically and know its usefulness and benefit for all concerned. It is still true today that '[r]eliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he [the physician] possesses the requisite qualifications.' Dent v. West Virginia, 129 U.S. 114, 122-123 (1889). See United States v. Vuitch, 402 U.S. at 71." (Doe v. Bolton,

supra, 410 U.S. 179, 199-200 [35 L.Ed.2d 201, 217, 93 S.Ct. 739, 751].)

In Whalen v. Roe, supra, 429 U.S. 589, the United States Supreme Court considered the New York statutory requirements with respect to prescriptions for "dangerous, legitimate" drugs. The requirement in question was that of notification. The court balanced the invasion of the zone of privacy against the public's right involved and concluded that with respect to the particular type of drugs involved the statutes were a reasonable exercise of the state's broad police power. In so holding the court discussed the right of an individual to choice of treatment saying: "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. . . . Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient." (Whalen v. Roe, supra, 429 U.S. 589, 603 [51 L.Ed.2d 64, 75-76, 97 S.Ct. 869, 878].)

Concerning the doctor's "right to practice" Whalen points out: "The appellee doctors argue separately that the statute impairs their right to practice medicine free of unwarranted state interference. If the doctors' claim has any reference to the impact of the 1972 statute on their own procedures, it is clearly frivolous. For even the prior statute required the doctor to prepare a written prescription identifying the name and address of the patient and the dosage of the prescribed drug. To the extent that their claim has reference to the possibility that the patients' concern about disclosure may induce them to refuse needed medication, the doctors' claim is derivative from, and therefore no stronger than, the patients'. Our rejection of their claim therefore disposes of the doctors' as well." (Italics added; Whalen v. Roe, supra, 429 U.S. 589, 604 [51 L.Ed.2d 64, 76, 97 S.Ct. 869, 879].)

Carey v. Populations Services Intern., ____U.S.____ [52 L.Ed.2d 675, 97 S.Ct. 2010], examines the question involving

the availability of contraceptives to minors. The Supreme Court held the right to privacy in matters affecting procreation extends to minors as well as adults.

The California Supreme Court has set forth as a "postulate" or "axiomatic" the right to choose one's own "lawful" treatment. In Cobbs v. Grant, 8 Cal.3d 229, at page 242 [104 Cal.Rptr. 505, 502 P.2d 1], the court, in determining the duty of the physician to secure the informed consent of the patient to treatment, said: "Preliminarily we employ several postulates. . . . The second is that a person of adult years and in sound mind has the right, in exercise of control over his own body, to determine whether or not to submit to lawful medical treatment."

Aden v. Younger, 57 Cal.App. 3d 662 [129 Cal.Rptr. 535], held unconstitutional the provisions of Welfare and Institutions Code section 5326.4 requiring substantive review by a mecial committee of a voluntary, competent patient's consent to choice of electroshock treatment. It was an unjustified

infringment of the patient's right to privacy. This court stated at page 684:

"Where informed consent is adequately insured, there is no justification for infringing upon the patient's right to privacy in selecting and consenting to the treatment. The state has varied interests which are served by the regulation of ECT, but these interests are not served where the patient and his physician are the best judges of the patient's health, safety and welfare.

". . . Any possible need which exists for the voluntary and competent patient cannot prevail in the face of the serious infringement to the patient's right to privacy as guaranteed by Roe v. Wade, supra, 410 U.S. 113 and Doe v. Bolton, supra, 410 U.S. 179." (Aden v. Younger, supra, 57 Cal.App.3d 662, 684.)

This right of choice-of-medical-treatment concept reached its quintessence in the Matter of Quinlan, 70 N.J. 10 [355 A.2d 674]. The New Jersey Supreme Court was called upon to determine whether the father, as guardian of

Karen Quinlan, a 21-year-old girl existing in a "persistent vegetative state," could be authorized to discontinue the extraordinary procedures sustaining the daughter's vital processes. The first question was: Did the comatose Karen Quinlan or her father have a right of choice to choose death or life? And secondly, could the father, through the court guardianship procedures, be authorized on her behalf to make such a choice. The court authorized, through the father-guardian, the withdrawal of the life support processes. The right of privacy inherent in the exceptional circumstances of that case authorized the rejection of the life support systems. Reasoned the court: "The claimed interests of the State in this case are essentially the preservation and sanctity of human life and defense of the right of the physician to administer medical treatment according to his best judgment. In this case the doctors say that removing Karen from the respirator will conflict with their professional judgment." (Matter of Quinlan, supra, 70 N.J. 10

[355 A.2d 647, 663].)

Yet, the court affirmed Karen's right to choice, had she been competent to assert it, and authorized the father to exercise it on her behalf: ". . . there would be no criminal homicide in the circumstances of this case. . . . even if it were to be regarded as homicide, it would not be unlawful." (Matter of Quinlan, supra, 70 N.J. 10 [355 A.2d 647, 669-670].) Concerning the interests of the state in preservation of human health and life the court said: "We have no hesitancy in deciding, in the instant diametrically opposite case, that no external compelling interest of the State could compel Karen to endure the unendurable, ..." (Matter of Quinlan, supra, 70 N.J. 10 [355 A.2d 647, 663].)

III

The Doctor's Zone of Privacy

Dr. Privitera asserts a separate and distinct constitutionally protected right -- a zone of privacy -- to prescribe, to treat patients whether in the

orthodox mode -- free from unjustified state interference.

Whalen v. Roe, supra, 429 U.S. 589, accepts as a premise the existence of the right of the individual patient to choose independently with the advice of his physician to use or not to use a particular medication. Said the Supreme Court at page 603 [51 L.Ed.2d at p. 75]: "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication." However, with respect to the doctor's right to freedom to treat, to minister to the sick, in Whalen v. Roe, supra, 429 U.S. 589, we have heretofore noted the Supreme Court's determination the "doctors' claim is derivative from, and therefore no stronger than, the patients'."

Doe v. Bolton, supra, 410 U.S. 179, however, speaks specifically of the doctor's right to administer medical care. Bolton involved a constitutionally defective statute requiring the consent of two state licensed physicians other

than the patient's own doctor before an abortion could be performed as well as advance approval of three members of the hospital staff where the abortion was to be performed. Concerning this statute the Supreme Court said: "The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." (Doe v. Bolton, supra, 410 U.S. 179, 197 [35 L.Ed.2d 201, 216, 93 S.Ct. 739 750]; italics added.)

Dr. Privitera additionally asserts an independent right to treat, not derived from or measured by his patient's right of choice, without first obtaining approval of the procedure or drug prescribed from a governmental board. He argues Health and Safety Code section 1707.1 invades this right. Again, as in the right of the patient, the doctor's asserted right must be first examined to determine its nature and thereby select the test, the degree of scrutiny to which the state interference will be

put. The right found must be balanced against the state -- the public interest protected.

Dr. Privitera's right, in relation to the patient, has been viewed traditionally as a species of economic interest rather than as "fundamental" akin to the privacy right. If a rational basis was found to support an encroachment, the statute was sustained.

While a dispassionate reading of the physician's licensing requirements raises some question concerning the total rationality of the licensing scheme, such standards are generally upheld as reasonable and necessary means of protecting the public health.

The more recent cases hint at the more profound right in the doctor. It is postulated: There exists in the doctor licensed to practice medicine a right, constitutional in nature, as yet ill-defined, to treat and to treat by unorthodox modalities -- as yet unapproved by the state board -- an informed consenting patient.

Doe v. Bolton, supra, 410 U.S. 179,

200 [35 L.Ed.2d 201, 217, 93 S.Ct. 739, 751], states if a physician is licensed by the state he is recognized by the state as capable of expressing acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are remedies available and "reliance must be placed on the assurance given by his license . . . that he possesses the requisite qualifications."

Roe v. Wade, supra, 410 U.S. 113, 163 [35 L.Ed.2d 147, 183, 93 S.Ct. 705, 732], states concerning the termination of pregnancy during the first trimester: ". . . the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that in his medical judgment, the patient's pregnancy should be terminated." (Italics added.)

Reason based on history, experience, supports the doctor's premise. To require prior state approval before advising -- prescribing-administering -- a new treatment modality for an informed consenting patient is to suppress in-

novation by the person best qualified to make medical progress. The treating doctor, the clinician, is at the cutting edge of medical knowledge.

To require the doctor to use only orthodox "state sanctioned" methods of treatment under threat of criminal penalty for variance is to invite a repetition in California of the Soviet experience with "Lysenkoism."5/ The mention of a requirement that licensed doctors must prescribe, treat, within

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5/ Soviet geneticist T.D. Lysenko, controversial dictator of "communistic" biology during the Stalin period, stultified the science of genetics in the U.S.S.R. for at least a generation. He imposed the "state sanctioned alternative," the curious idea that environmentally acquired characteristics of an organism could be transmitted to the offspring through inheritance. Thus, the Stalinist concept of ideological conformity politically implanted in genetics paralyzed this important branch of Soviet science.

"state sanctioned alternatives" raises the spector of medical stagnation at best, statism, paternalistic Big Brother at worst. It is by the alternatives to orthodoxy that medical progress has been made. A free, progressive society has an enormous stake in recognizing and protecting this right of the physician.6/

6/ Lest the reader suspect these conclusions are alarmist, without relevance to here and now, reference is made to Drug Regulation and Innovation -- Empirical Evidence and Policy Options, by Henry G. Grabowski (1976). This is a summary of studies made -- cost versus benefit analysis of the effects of the 1962 amendment which clothed the Federal Drug Administration with the authority to test new drugs for their "effectiveness" before permitting general prescription and use.

One study surveyed was that by Sam Peltzman. He researched the effect of the 1962 amendment on drug innovation: "In effect, Peltzman's . . . suggests that the rate of innovation in the post-amendment period is more than halved as a result of the 1962 amendments."

Did the Federal Drug Administration effectively weed out ineffective drugs? Peltzman's study shows: ". . . analysis of evaluations by medical experts suggests that the proportion of ineffective drugs has remained roughly the same

(Fn. 6 continued.)

(Fn. 6 continued.)

in the pre-1962 and post-1962 periods. Given that the rate of new drug introductions was more than halved in the post-amendment period, his analysis therefore suggests that a large decline took place in effective drugs." (Italics added.)

The conclusion reached by Professor Grabowski: "A consistent finding is that regulation has had a significant negative effect on the rate of innovation. While each of the individual studies has shortcomings, taken together they would seem to provide considerable support for the hypothesis that regulation has been one of the principal factors responsible for the observed decline in innovation."

Professor Grabowski's study shows: "An indication of the change is the decline in discovery and development of new chemical entities by U.S. firms -- an initial decline from more than one-third of worldwide introductions in the year before the 1962 amendments to the Food, Drug, and Cosmetic Act to less than one-quarter of the total in 1963 . . . and unfortunately, as Professor Grabowski shows, a continued erosion of U.S. leadership thereafter. We have reached the point where innovations based on discoveries by U.S. firms and institutions constitute less than one-sixth of world-wide introductions of new chemical entities . . . and exports of pharmaceuticals as a share of U.S. exports have declined by one-third since the 1950s."

(Fn. 6 continued.)

(Fn. 6 continued.)

Decline in innovation is bad enough yet the public's safety has not been enhanced. According to Professor Grabowski: "One of the bitter ironies of this situation is that the 1962 amendments were spurred by an alarm over the safety of new drugs -- by the fears created by the thalidomide incident. The irony lies in the fact that the 1972 amendments are keeping off the market new drugs that are safer than the drugs they would replace. Professor William Wardell's study of the lags in the introduction of new drugs in the United States cites, as one example, the five-year delay in the appearance on the U.S. market of a benzodiaze-pine hypnotic. If it had been available in the United States as it was in Great Britain during those five years, Professor Wardell estimates that 1,200 lives would have been saved.5/"

"5/ William M. Wardell, 'Therapeutic Implications of the Drug lag,' Clinical Pharmacology and Therapeutics, vol. 15, no. 1 (January 1974), p. 83." (Henry G. Grabowski, Drug Regulation and Innovation -- Empirical Evidence and Policy Options, p. 2.)"

IV

The Right of Privacy -- Article I, Section 1, of the California Constitution

Thus far we have considered only the specific guarantees of the federal bill of rights and the emanations formed therefrom in concluding fundamental rights are encroached by section 1707.1 However: "'[I]n the area of fundamental civil liberties -- which includes . . . all protections of the California Declaration of Rights -- we sit . . . subject only to the qualification that our interpretations may not restrict the guarantees accorded the national citizenry under the federal charter. In such constitutional adjudication, our first reference is California law and the full panoply of rights Californians have come to expect as their due. Accordingly, decisions of the United States Supreme Court defining fundamental rights are persuasive authority to be afforded respectful consideration, but are to be followed by California courts only when they provide no less indivdual

protection than is guaranteed by California law.'" (Serrano v. Priest, 18 Cal.3d 728, 764, [135 Cal.Rptr. 345, 557 P.2d 929] quoting People v. Longwill, 14 Cal.3d 943, 951, fn. 4 [123 Cal.Rptr. 297, 538 P.2d 753].) (See also People v. Disbrow, 16 Cal.3d 101, 114-115 [127 Cal.Rptr. 360, 545 P.2d 272]; People v. Norman, 14 Cal. 3d 929, 939 [123 Cal.Rptr. 109, 538 P.2d 237]; People v. Brisendine, 13 Cal.3d 528, 548-552 [119 Cal.Rptr. 315, 531 P.2d 1099]; Burrows v. Superior Court, 13 Cal.3d 238, 245-246 [118 Cal.Rptr. 166, 529-P.2d 590]; Mandel v. Hodges, 54 Cal.App.3d 596, 615-617 [127 Cal. Rptr. 244]; State v. Kaluna, 55 Hawaii 361 [520 P.2d 51, 58-59]; Baker v. City of Fairbanks, 471 P.2d 386, 401-402; see generally Note, Project Report: Toward an Activist Role for State Bills of Rights (1973) 8 Harv.Civ.Rights -- Civ. Lib.L.Rev. 271; Falk, Foreword: The State Constitution: A More than "Adequate" Nonfederal Ground (1973) 61 Cal.L.Rev. 273; Note, Rediscovering the California Declaration of Rights (1974) 26 Hastings L.J. 481.)

It is an "incontrovertible conclusion that the California Constitution is, and always has been, a document of independent force. Any other result would contradict not only the most fundamental principles of federalism but also the historic bases of state charters." (People v. Brisendine, supra, 13 Cal.3d 528, 549-550.) We therefore must evaluate the rights infringed by section 1707.1 in light of our own Constitution.

Article I of the state charter is the California Declaration of Rights. Its first section establishes certain inalienable rights: "All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing and protecting property, and pursuing and obtaining safety, happiness, and privacy." (Italics added.) "The [federal] Constitution does not explicitly mention any right of privacy." (Roe v. Wade, supra, 410 U.S. 113, 152 [35 L.Ed.2d 147, 176, 93 S.Ct. 705, 726].) Neither did the California Constitution. However, "[i]n November

1972, the voters of California specifically amended article I, section 1 of our state Constitution to include among the various 'inalienable' rights of 'all people' the right of 'privacy.'" (White v. Davis, 13 Cal.3d 757, 773 [120 Cal.Rptr. 94, 533 P.2d 222].)

The California Supreme Court first addressed the significance of the new provision in White v. Davis, supra, 13 Cal. 3d 757, 773-776. In that case the complaint asserted certain government surveillance and data-gathering activities abridged students' and teachers' constitutional right of privacy. In reversing a judment entered upon the sustaining of a general demurrer, the court concluded the activities challenged did fall within the aegis of article I, section 1. The court "intimate[d] no opinion as to the resolution of the ultimate constitutional question after trial" (White v. Davis, supra, 13 Cal.3d 757, 776), and did not purport to sketch "the full contours of the new constitutional provision." (Id., at p. 773.) Nevertheless, we are aided by its observations and analysis.

"The principal objectives of the newly adopted provision are set out in a statement drafted by the proponents of the provision and included in the state's election brochure." (Id., at p. 774.) This statement represents, in essence, the only "legislative history" of the constitutional amendment available (id., at p. 775), and "California decisions have long recognized the propriety of resorting to such election brochure arguments as an aid in construing legislative measures and constitutional amendments adopted pursuant to a vote of the people." (Id., at fn. 11.)

After review of the ballot statements in White v. Davis, supra, 13 Cal.3d 757, the Supreme Court concluded: "Although the general concept of privacy relates, of course, to an enormously broad and diverse field of personal action and belief, the moving force behind the new constitutional provision was a more focussed privacy concern, relating to

the accelerating encroachment on personal freedom and security caused by increased surveillance and data collection activity in contemporary society. The new provision's primary purpose is to afford individuals some measure of protection against this most modern threat to personal privacy." (Id., at pp. 773-774.)

The rights here relied upon by Privitera do not fall within that "more focused privacy concern" of White v. Davis, supra, 13 Cal.3d 757; but rather relates to the "enormously broad and diverse field of personal belief and action." The state here does not seek to surveil or collect data about laetrile users or distributors. It seeks to circumscribe an even more profound compelling interest, that right which is but an "outward manifestation of the inward domain of the consciousness," the right to be left alone.

To find the legislative intent of the people of the State of California in enacting the amendment to article I, section 1, we look to the language of

the election brochure which extends beyond data collection into the broader area of freedom of personal action and belief. The argument in favor of the amendment stated:

"The right of privacy is the right to be left alone. It is a fundamental and compelling interest. It protects our homes, our families, our thoughts, our emotions, our expressions, our personalities, our freedom of communion, and our freedom to associate with the people we choose.

". . . . . .

"The right of privacy is an important American heritage and essential to the fundamental rights guaranteed by the First, Third, Fourt, Fifth and Ninth Amendments to the U.S. Constitution. This right should be abridged only when there is compelling public need." (Italics added.)

The proponents of the amendment further stated (in rebuttal): "The right to privacy is much more than 'unnecessary wordage.' It is fundamental in any free society. Privacy is not now guar-

anteed by our State Constitution. This simple amendment will extend various court decisions on privacy to insure protection of our basic rights." (Italics added.)

This "legislative history" closely parallels the thoughts -- uses the exact words -- of Justice Brandeis in his prescient dissent in Olmstead v. United States, supra, 277 U.S. 438.7/

7/ As if he had this case in mind, Brandeis insightfully cautioned: "Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding." (Olmstead v. United States, supra, 277 U.S. 438, 479 [72 L.Ed. 944, 957, 48 S.Ct. 564, 572-573]; Brandeis, J., dissenting.)

Like Brandeis, the people of California have recognized the right to be left alone -- the right to be free in the sphere of private action. It is "fundamental." It protects "our homes, our families, our thoughts, our emotions, our expressions, our personalities . . . ."8/

8/ Philosopher John Stuart Mill in his classic work On Liberty (George Routledge 1905) sets forth the philosophic underpinnings for this recently enunciated right to be left alone:

"[T]here is a sphere of action in which society, as distinguished from the individual, has, if any, only an indirect interest; comprehending all that portion of a person's life and conduct which affects only himself, or if it also affects others, only with their free, voluntary, and undeceived consent and participation. When I say only himself, I mean directly, and in the first instance; for whatever affects himself, may affect others through himself; . . . . This, then, is the appropriate region of human liberty. It comprises, first, the inward domain of consciousness; demanding liberty of conscience, in the most comprehensive sense; liberty of thought and feeling; absolute freedom of opinion and sentiment on all subjects, practical or speculative, scientific, moral, or theological. . . . Secondly, the principle requires liberty of tastes and pursuits; of framing the plan of our life to suit

(Fn. 8 continued.)

Based upon the "legislative intent" derived from the express language of the election brochure we conclude a right, of California constitutional dimension, was enacted. This right is not just a shield against threats to personal freedom posed by modern surveillance and data collecting activities. This state-protected right of privacy encompasses a fundamental and compelling interest of the cancer patient to choose or reject his or her own medical treatment on the advice of a licensed medical doctor. This right can be abridged only where there is compelling need.

(Fn. 8 continued)

our own character; of doing as we like, subject to such consequences as may follow: without impediment from our fellow-creatures, so long as what we do does not harm them, even though they should think our conduct foolish, perverse, or wrong . . . .

". . . The only freedom which deserves the name, is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it. Each is the proper guardian of his own health, whether bodily, or mental and spiritual. Mankind are greater gainers by suffering each

(Fn. 8 continued.)

V

The Nature of the State's Interest

We have established this premise: The patient's and Dr. Privitera's rights of privacy are of such magnitude only a compelling state interest can justify intrusion in the patient-doctor treatment setting. We now consider the strength of that state interest. Does Health and Safety Code section 1707.1 serve a compelling state interest which overrides the rights so found?[9/] Indeed, a state has a profound interest in maintaining medical standards and in protecting health, life. This justifies the test-

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(Fn. 8 continued.)

other to live as seems good to themselves, than by compelling each to live as seems good to the rest."

Mill concludes "over himself, over his own body and mind, the individual is sovereign." (Pp. 13-18.)

9/ John Stuart Mill, On Liberty, supra, gives substance to the concept of "compelling state interest" when he asserts: ". . . one very simple principle, as entitled to govern absolutely the dealings of society with the in-

(Fn. 9 continued.)

(Fn. 9 continued.)

dividual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties, or the moral coercion of public opinion. That principle is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. These are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him, or visiting him with any evil in case he do otherwise. To justify that, the conduct from which it is desired to deter him, must be calculated to produce evil to some one else. The only part of the conduct of any one, for which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign."

ing and licensing of doctors and the limits on giving of medical advice by qualified practitioners. The regulation of pharmaceuticals, the licensing requirements for pharmacists and other dispensers of drugs are so authorized. Harm to others is readily forseeable. It is well settled the state has broad police powers in regulating the administering of certain types of drugs by the health professions. (See Robinson v. California, 370 U.S. 660, 664-665 [8 L.Ed.2d 758, 761-762, 82 S.Ct. 1417, 1419-1420]; Minnesota ex rel. Whipple v. Martinson, 256 U.S. 41, 45 [65 L.Ed. 819, 822, 41 S.Ct. 425, 426]; Whalen v. Roe, supra, 429 U.S. 589.)

The cases cited by the People in support of this unquestioned power of the state uniformly involve drugs which are narcotic, habit forming, toxic in nature. For example, as noted in Whalen v. Roe, supra, the New York Legislature had enacted a statutory scheme regulating dangerous, legitimate, drugs such as opium, cocaine, methadone. The state could "prohibit entirely [their] use."

Therefore, the New York statute requiring the doctor to furnish the state with a copy of every prescription for such drugs did not unconstitutionally deprive a person of the right to decide independently with the advice of his physician to acquire or to use needed medication.

In Minnesota ex rel. Whipple v. Martinson, supra, 256 U.S. 41, 45 [65 L.Ed. 819, 822, 41 S.Ct. 425, 426], the Supreme Court reiterated this premise when examining a California statute which regulated morphine stating: "There can be no question of the authority of the state in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs, such as are named in the statute. The right to exercise this power is so manifest in the interest of the public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be successfully called in question."

In Blinder v. Division of Narcotic

Enforcement, supra, 25 Cal.App.3d 174, 181, the authority of the State of California to regulate prescription by a doctor of a narcotic, habit forming, dangerous drug was vindicated. Plaintiff physician sought to prescribe the use of methadone as a necessary and effective method for the treatment of narcotic addiction. The statutes challenged by Dr. Blinder provided for treatment of addicts at certain places and specified periods of time and limited use of methadone in the treatment of other diseases. The court in Blinder held the limitations upon the prescription of methadone for treatment of addicts (Health & Saf. Code, §§ 11391 and 11395) were an appropriate exercise of the police power of the state and did not constitute a denial of equal protection of law or constitute cruel and unusual punishment. Concerning the right of the doctor to practice without state interference, Blinder v. Division of Narcotic Enforcement, supra, 25 Cal.App.3d 174, at page 181, states: "It is well established, moreover, that

although the right to practice medicine, like the right to practice any other profession, is a valuable property right [citation], this right may not be exercised free of reasonable restrictions. 'The state clearly has the power to regulate professions in the interest of public health, safety and welfare.' [Citations.]" It should be noted in Blinder, as in Whipple, as in Robinson, and in Whalen v. Roe, supra, the drugs subject to his broad police power are drugs which are dangerous in the sense that they are narcotic, habit forming, hallucinatory or toxic. Their use or misuse "concerns others." Laetrile is not in this class. It is generally conceded to be a harmless drug. Its alleged evil lies in its "ineffective" treatment of cancer.

The sole case authority submitted for the proposition that the state has the right under its police power to interfere in the doctor-patient relationship where the drug prescribed is amygdalin is People v. Privitera, 55 Cal.App.3d Supp. 39 [128 Cal.Rptr. 151], where the

same Dr. Privitera was charged in the Municipal Court of Los Angeles with a series of misdemeanor violations of section 1707.1 (here charged as the substantive crime, the object of a felony conspiracy). The trial court there sustained defendant's demurrer on the ground section 1707.1 was unconstitutional. The Appellate Division of the Superior Court of Los Angeles County reversed and denied section 1707.1 was overbroad, arbitrary or unreasonable. It was within the constitutional power of the Legislature to prohibit the prescription of amygdalin for cancer treatment. For its authority the appellate division relied upon the cases we cite which warrant state intervention in the doctor-patient area in the control, distribution, use of narcotics and other dangerous drugs.

The Privitera court examined the procedure imposed by the Legislature for the prior administrative determination of whether the drug is recognized as safe and effective. For approval thereof, Privitera relies on the United

States Supreme Court in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 619 [37 L.Ed.2d 207, 217, 93 S.Ct. 2469, 2478], which held in passing upon the safety and efficacy of new drugs, strict scientific standards must be employed and not "anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug." Concerning the problem of whether the scientific and medical authorities are in dispute the appellate division stated: "'Where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not generally recognized as safe for the use in the treatment of that disease.' (United States v. Article of Drug, etc. (N.D. Ga. 1968) 294 F.Supp. 1307, 1311.)" (People v. Privitera, supra, 55 Cal. App.3d Supp. 39, 51.)

The appellate division examined the right of privacy question but found the state interest to be of such magnitude

as to authorize prohibition of all treatment by physicians of cancer by any modalities other than "state sanctioned alternatives." Said People v. Privitera, supra, 55 Cal.App. 3d Supp. 39, 52: "However, the California Legislature, in enacting the statutory scheme of cancer regulations, made the implicit finding that alleged but ineffective cancer remedies are more hazardous to the patient than the state-sanctioned alternatives. We believe such finding to be reasonable. One desperate for a cure but who seeks to avoid necessary surgery because it is disfiguring, necessary radiation because it is debilitating or necessary chemotherapy because it is toxic, might in his extremity employ substances which are represented to be both harmless and curative. Knowing such propensity of these seriously ill, the Legislature exercised its police power to protect its citizens from the allegedly easier but fallacious cure." (Italics added.)

Reported cases specifically involving the authority, the right, of either the

federal government or state to penalize, prohibit, amygdalin transportation, possession or use are rare. In Rutherford v. United States, 399 F.Supp. 1208, a class action was brought by cancer victims seeking to compel the Federal Drug Administration (FDA) to desist from precluding administration of amygdalin to patients suffering from cancer. By its nonaction, it was contended, the FDA made amygdalin not available. Rutherford sought medical advice in the United States. He was advised of the necessity of abdominal resection, removal of his rectum. He rejected these alternatives and sought laetrile treatment at a medical clinic in Tijuana, Mexico. There he was treated for a period of weeks and was returned as cured. He alleged without the continued use of the amygdalin he faced the prospect of escalation of the carcinoma.

The district court in Rutherford v. United States, supra, found that the FDA, under 21 United States Code section 355, had: ". . . abdicated its duty to

make a clear determination of whether the drug laetrile should or should not be placed in commerce though the drug has been in use for many years and thousands of persons have been treated with it."

The court further found that from the records, testimony and exhibits that: ". . . laetrile is not lethal in any sense of the word. It is not harmful to the human body and when used in proper amounts under proper control and supervision can effect relief from cancer disease to the satisfaction of many who are privileged to use the same." (Rutherford v. United States, supra, 399 F.Supp. 1208, 1212.) In view of this failure of the Federal Drug Administration to act in accordance with the constitutional intent, the court found that Rutherford and others were wholly without means or resources to comply with the provisions of 21 United States Code section 355(b),[10/] further that

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10/ 21 United States Code section 355 provides in part: "(a) No person shall introduce or deliver for introduction into interstate com-

(Fn. 10 continued.)

each of them was denied "the freedom of choice for treatment by laetrile to alleviate or cure their cancer."

Basing its decision upon the Roe v. Wade, supra, 410 U.S. 113, concept of the right of privacy as one of the rights formed by the emanations from the guarantees of the Fifth and Fourteenth Amendments, the court granted the requested injunctive relief.

Rutherford was reviewed sub nomine Stowe v. United States of America (10-12-75) D.C. No. CIV-75-0218-B (10th Cir.).[11/] The court of appeals de-

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(Fn. 10 continued)

merce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug."

11/ Stowe was the original plaintiff in the Rutherford case. He was a cancer patient and died in the pending of the suit. Rutherford and Mrs. Schneider filed further papers in the proceedings. Mrs. Schneider, Rutherford's co-plaintiff, died before the hearing on the preliminary injunction which was issued by the district court.

clined to review the district court's rulings laetrile was an effective treatment for cancer, was not toxic, and the new drug application provision, 21 United States Code section 355(a), was unconstitutional. Rather the court of appeals confined itself to the issue of whether the laetrile was a so-called "new drug" requiring FDA approval. The court of appeals held that the record made before the trial court was not sufficient but concluded the "preliminary injunction granted by the district court in this case should be and the same is upheld." (Italics added.)

After remand to the district court in opinion filed January 4, 1977, it was held: "In view, however, of the complete absence of any good-faith agency record in support of its position in this case, as the record here is not merely incomplete, but virtually nonexistent; and in appreciation of the fact that de-

priving a terminally ill cancer patient of a substance he finds therapeutic, whether such benefit is physical or psychological, creates the very risk that irreparable injury might be sustained."

The district court injunction remains in effect pending remand to the FDA.

In Carnohan v. United States of America, et al., United States District Court, Southern District of California (San Diego), Civil No. 77-0010-GT, plaintiff was a terminal cancer patient. He sought to enjoin the FDA's interference with his importation or interstate transportation of amygdalin for his own consumption.

The court found Carnohan was receiving laetrile in Mexico, and in order to receive the drug he must either choose to live in Mexico or he must commute daily for his treatment. The court weighed its basic authority for the issuance of injunctive relief against the harm to the public that could possibly occur by weakening laws calcu-

lated to prevent victimization of cancer victims by playing on their desperate need. The court observed where a person is terminally ill with cancer and unresponsive to other treatments: ". . . the public harm is considerably reduced. Such a person would not be avoiding other methods of treatment generally [accepted] . . . ." Thereupon the court enjoined the United States Customs Service from interfering in Carnohan's possession and moving in interstate commerce not in excess of a three-month supply of laetrile pending completion by the FDA of its study.

These judically carved out exceptions to the federal prohibition against importation or interstate transportation of amygdalin rest upon an unarticulated premise. No compelling state interest required enforcement of the laetrile ban in the recited circumstances.

VI

Conclusions

We turn now to the final, the pivotal question: Does the imposition of crimi-

nal sanction on the doctor for prescribing amygdalin as a cancer treatment for an informed consenting cancer victim, without first seeking governmental approval of its safety and effectiveness, serve a compelling state interest?

The Legislature has found the state's compelling interest derives from its "interest" in the "effective diagnosis, care, treatment or cure of persons suffering from cancer." (Health & Saf. Code, § 1700.) Further the Legislature found: ". . . accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven . . . reduces the likelihood of death from cancer . . . ." The People argue these are compelling reasons to deny cancer victims the prescriptions by a doctor of as yet an unapproved drug.

Without question, Health and Safety Code section 1707.1 is an attempt at exercise of legislative power in the area of public health to protect the cancer victim. The legislative concern expressed in section 1700 reflects a

well founded and appropriate concern for misleading and false claims of cures for cancer. The section states a truism when it finds: "Various persons in this State have represented and continue to represent themselves as possessing medicines, . . . skills, . . . for the effective diagnosis, treatment, or cure of cancer, which representations are misleading to the public, ..."

However, upon what factual basis duly licensed doctors in the State of California are chargeable, let alone found guilty of the strictures made in the legislative finding is not clear. Why doctors, "recognized by the State as capable of exercising acceptable clinical judgment," are honored by being encompassed within that invidious class of "various persons" who "mislead" the public is obscure. "The . . . suggestion is necessarily somewhat degrading to the conscientious physician, . . . He, perhaps more than anyone else, is knowledgeable in this area of patient care, and he is aware of human frailty, . . . and needs." (Doe v. Bolton, supra, 410

U.S. 1979, 196 [35 L.Ed. 2d 201, 215, 93 S.Ct. 739, 750].)

The legislative finding gives no hint of what rational classification includes medical doctors within the ambit of quacks.

The doctor in California is licensed to practice only after meeting long rigid education, experience qualifications. He is bound by oath to preserve, to prolong, the life of his patient. He is under a legal duty, under threat of malpractice suit, to act in accordance with the generally accepted standards of medical practice in his community in this state. He is required under threat of malpractice to treat only after receiving the informed consent of the patient. (Cobbs v. Grant, supra, 8 Cal.3d 229.) These are the "rational means" society through law has imposed to insure a high standard of performance by the California doctor. It follows after such rigid standards are met, the matter of choice of treatment of the informed consenting patient becomes "a purely medical determination, which is within

a doctor's professional judgment." (Aden v. Younger, supra, 57 Cal.App.3d 662, 677.) "Reliance must be placed upon the assurance given by his license, . . . that he possesses the requisite qualifications." (Dent v. State of West Virginia, 129 U.S. 114, 122-123 [32 L.Ed. 623, 626, 9 S.Ct. 231, 233].)

Limiting this exercise of the doctor's professional judgment on some vague suspicion that "various persons" in this state are engaging in quackery does not follow as a matter of logic.

The premise that "various persons," -- con man, snake oil salesman, -- have made or will make false and misleading representations to the public concerning the diagnosis, treatment and cure of cancer certainly warrants, as rational means, the law which prohibits and makes criminal such acts. Health and Safety Code section 1714 accomplishes this precise purpose. It prohibits a false representation with intent to defraud of any device or substance or treatment as an effective cure for cancer. Dr. Privitera does not contest the appropriate-

ness of Health and Safety Code section 1714 as it does fit the announced legislative purpose.

We conclude the limitation upon the right to prescribe, to treat, of the doctor of section 1707.1 bears no logical relationship to the expressed legislative purpose. A fortiori, if there is a lack of reasonable relationship between the end sought and the means used, then certainly no compelling state purpose is present.12/

12/ Refusing enforcement of Health and Safety Code section 1707.1 is totally compatible with (1) compulsory vaccination, (2) fluoridation of public water supplies, (3) requiring that certain drugs be available to the public on prescription from a licensed doctor, and (4) recognition of a compelling state interest in the health of a prospective mother at approximately the end of the first trimester of pregnancy. (Roe v. Wade, supra, 410 U.S. 113.) Philosopher Mill precisely located the line of demarcation between the individual's control of himself, his own body and mind, and the sovereignty, retained by the state saying "there is a sphere of action in which society, as distinguished from the individual, has if any, only an indirect interest." (John Stuart Mill, On Liberty, supra.) The much quoted Homes' observation that freedom of speech does not

(Fn. 12 continued.)

Dr. Privitera is charged under Health and Safety Code section 1707.1. This statute requires for its breach an intent to prescribe the unauthorized drug or medicine for treatment of cancer. The efficacy of the treatment proposed or medicine prescribed is not an issue under this statute. The truth or veracity of the representations, disclosures, discussions, made in connection with the treatment, by the doctor to the patient are not an issue in a trial of charges made under section 1707.1.

The criminal liability attaches because the doctor in the exercise of his medical judgment has prescribed a drug for treatment of cancer not yet approved under section 505 of the federal Food, Drug and Cosmetic Act or

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(Fn. 12 continued)

encompass the right to shout fire in a crowded theater rests upon the readily recognizable danger to society and thus authorizes state intervention. Roe v. Wade, supra, 410 U.S. 113, is a classic example of a silent application of the Mill reasoning by the United States Supreme Court in delienating the line between the mother's control over her own body and a public interest when there is another life and being.

which has not yet received approval of the state board. Whether the doctor in his best medical judgment believes he has a miracle drug, a food supplement or a hope-giving placebo is not an issue. The governmental agencies have not given approval; therefore the doctor cannot prescribe.

The patient's right to receive medical care, and the doctor's right to administer it are substantially limited not because of some established defect in the medication, some danger to the public if this patient is so treated. The doctor becomes a criminal because the government agency has not given its prior approval to the exercise of his best medical judgment.

The statute must be measured against the legislative purpose of frustrating cancer quacks, and for the promotion of the early effective care, diagnosis and cure of cancer. Instead, the immediate and most direct effect of the prohibition of section 1707.1 is to chill, to prevent, innovative treatment by a licensed doctor, the person or in the

class of persons most likely to make the hoped-for breakthrough against dreaded cancer. How logically this threat to the innovative physician will increase early effective diagnosis and cure of cancer is difficult to perceive.

People v. Privitera, supra, 55 Cal. App.3d Supp. 39 at page 52 of the supplement makes the following remarkable observation concerning that compelling state interest which supports Health and Safety Code section 1707.1:

". . . ineffective cancer remedies are more hazardous to the patient than the state-sanctioned alternatives."

(Italics added.)

The Legislature has not made such an express finding and if such finding should be implied then it denies the patient the exercise of one of his most fundamental rights. He, instead, has the choice of "state sanctioned" treatment by the doctor or no treatment from the doctor at all. Again, if this be the legislative purpose, it misses its mark. Diminishing fraudulent cures,

punishing quackery in cancer treatment, is a laudible objective. The means chosen by the Legislature is bureaucratically predetermined treatment or none, injected into a constitutionally protected area of privacy. This fundamental right of privacy, this right to be left alone, is "older than the Bill of Rights, older than our political systems." It cannot be swept away, denied by the processes of compelled acceptance of "state sanctioned alternatives."

It may be conceded that the dangers of treatment of cancer -- or of any serious and disabling disease -- by nonlicensed purveyor of medical services is fraught with dangers to the public and properly subject to legislative protection. Thus the difficulty with the statute as here applied is that it seeks to remedy the danger (that of a licensed medical doctor prescribing a treatment of a cancer patient without first getting approval of an administrative body) when that danger is not yet shown to exist.

If it be conceded section 1707.1 would theoretically assure some protection to

the public or that unfortunate portion of the public who have cancer but who have not yet heard of the need for early treatment, by prohibiting the use of amygdalin or any unapproved modality by the licensed physician, yet under the law of this state and the United States any individual can possess, use, self-treat, his condition, whatever it may be, by use of amygdalin, to his heart's content without liability.[13/] In effect it turns the whole matter of treatment

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13/ See Ellen S. Hodgson, infra, page 687, footnote 240, pointing out this incongruity. The smuggler of laetrile: ". . . faced a $10,000 fine and five-year prison sentence -- the maximum penalty imposed for smuggling an illegal drug intended for resale in the United States. See 18 U.S.C. § 545 (1970). That only the supplier, not the possessor, of laetrile is subject to criminal prosecution is due to the fact that the drug is not clasified as a 'controlled' substance -- like heroin or marijuana -- the possession of which is illegal. However, because the FDA has not officially recognized the drug as 'safe,' it cannot be brought into the country or transported across state lines."

back to the cancer patient himself if he is unwilling to accept the "state sanctioned alternatives."

We conclude not only is there no compelling reason shown to override the patient's or the doctor's fundamental right of choice in the treatment setting but that the statute when sought to be applied to a licensed medical doctor does not pass the test as a rational means of accomplishment of the announced legislative purpose.

There remains one further concern. The evidence in this case shows without exception the cancer victims, whether People's or defense's witnesses, were knowledgeable persons fully aware of the nature of the "state sanctioned alternatives" before seeking treatment from Dr. Privitera. Many were unwilling to accept the orthodox alternatives; many unwilling to accept the verdict of "terminal." These are not wide-eyed country bumpkins seeking to be conned. The class actions filed against governmental authorities to compell the

availability of the drug in question illustrate the desperate seeking of the cancer victims.[14/] We need cite only one witness as a basis for a composite picture: The patient is a "senior" citizen with diagnosed cancer of the prostate; treatment recommended -- prostate removal and castration; female hormone treatment for the rest of his life. The victim simply refused to accept these alternatives and sought amygdalin treatment.

The nineteen witnesses testifying for Dr. Privitera conveyed a felt imminency of death. One senses a mortal fear of both the disease and the orthodox alternatives. This is a desperate utterly human seeking to avoid the pain and to prolong life. These elements form the unspoken rationale of the Rutherford and Carnohan decisions.

14/ See Ellen L. Hodgson, Restrictions on Unorthodox Health Treatment in California: A Legal and Economic Analysis, 24 UCLA L. Rev. 647, 683, 689, for an excellent and exhaustive review of case and statutory law.

Matter of Quinlan, supra, 70 N.J. 10 [355 A.2d 647, 663], states the premise eloquently: ". . . no external compelling interest of the State could compel Karen to endure the unendurable, only to vegetate a few measurable months with no realistic possibility of returning to any semblance of cognitive or sapient life. We perceive no thread of logic distinguishing between such choice on Karen's part and a similar choice which, under the evidence in this case, could be made by a competent patient terminally ill, riddled by cancer and suffering great pain; such a patient would not be resuscitated or put on a respirator . . . and a fortiori would not be kept against his will on a respirator."

To these nineteen cancer victims the enforcement of Health and Safety Code section 1707.1, the denial to them of medical treatment, albeit unorthodox, albeit unapproved by a state agency, must surely take on a Kafkaesque, a nightmare, quality. No demonstrated public danger, no compelling interest

of the state, warrants an Orwellian intrusion into the most private of zones of privacy.

The state has in the name of protecting the cancer victim criminalized the doctor who is willing to innovate, willing to try an unapproved drug with the consent of his patient. From the terminal patient's viewpoint a new depth of inhumanity is reached by a broad sweep of this law so interpreted. No compelling interest of the state requires Dr. Privitera's 19 cancer patients to endure the unendurable, to die, even forbidden hope.

Health and Safety Code section 1707.1 as here sought to be applied invades the patient's and the doctor's zone of privacy without showing of external compelling state interests in violation of the Fourteenth Amendment to the federal Constitution and articles I, section 1 of the California Constitution."

BIRD, C.J.

PEOPLE v. PRIVITERA

Crim. 20340

DISSENTING OPINION BY NEWMAN, J.

I join in the Chief Justice's dissent, except that I would not rely on the federal Constitution. What the majority of my colleagues condone here is action that appears to me to constitute cruel and inhuman treatment. (Cf. diss. opn. in Cramer v. Tyars, 23 Cal.3d 131, 151, fn. 1. See too Rosenblatt, Health Care Reform and Administrative Law: A Structural Approach (1978) 88 Yale L.J. 243, 247 ["The Legal Structure of Health Care Reform: Creating the Appearance of Public Control"].)

By selective quotation the majority opinion downgrades the right of privacy in California, which "relates, of course, to an enormously broad and diverse field of personal action and belief . . . ." (White v. Davis (1975) 13 Cal.3d 757, 774.) What the Califor-

nia Constitution in article I, section 1, guarantees is an inalienable right of "pursuing and obtaining safety, happiness, and privacy." By no means do those words merely mirror Unites States Supreme Court opinions. In White v. Davis, supra, Justice Tobriner's opinion for a unanimous court noted approvingly these statements from the official election brochure that help illuminate privacy's full scope: "'The right of privacy is the right to be left alone. It is a fundamental and compelling interest. It protects our homes, our families, our thoughts, our emotions, our expressions, our personalities, our freedom of communion and our freedom to associate with the people we choose . . . .'" (Id. at p. 774.) "'The right of privacy is an important American heritage and essential to the fundamental rights guaranteed by th First, Third, Fourth, Fifth and Ninth Amendments to the U.S. Constitution. This right should be abridged only when there is a compelling public need. . . .'"

In this case I detect no such need.

NEWMAN, J.

APPENDIX B

B-1

ORDER DENYING REHEARING

CLERK'S OFFICE, SUPREME COURT
4250 STATE BUILDING
SAN FRANCISCO, CALIFORNIA 94102

APR 12 1979

I have this day filed Order

REHEARING DENIED

In re: Crim. *No.* 20340

People

vs.

Privitera, Jr., et al.

Respectfully,

G. E. BISHEL
Clerk

68983-877 11-78 4M OSP

APPENDIX C

STATE COURT OF APPEAL
FOURTH DISTRICT
STATE OF CALIFORNIA

Cr. 8323.

[Filed November 10, 1977]

THE PEOPLE OF THE STATE OF CALIFORNIA,
Plaintiff and Respondent,

v.

JAMES ROBERT PRIVITERA, JR., et al,
Defendants and Appellants

"Under California Health and Safety Code section 1707.1,[1/] it is a misdemeanor to sell, deliver, prescribe or administer any drug or device to be

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1/ Health and Safety Code section 1707.1 provides:

"The sale, offering for sale, holding for sale, delivering, giving away, prescribing or administering of any drug, medicine,

(Fn. continued)

(Fn. 1 continued)

compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application with respect thereto has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act [21 USCS § 355], or (2) there has been approved an application filed with the board setting forth:

"(a) Full reports of investigations which have been made to show whether or not such drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use;

"(b) A full list of the articles used as components of such drug, medicine, compound or device;

"(c) A full statement of the composition of such drug, medicine, compound or device;

"(d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of

used in the diagnosis, treatment, alleviation or cure of cancer which has not been approved by the designated federal agency (21 U.S.C.S. § 355) or by a state board (Health & Saf. Code, § 1704).

Defendants, James Robert Privitera, Jr., a medical doctor, William David Turner, Phyllis Blanche Disney, Winifred Agnes Davis, and Carroll Ruth Leslie, were convicted by jury of a felony, conspiracy to sell, to prescribe, an unapproved drug, laetrile, intended for the alleviation or cure of cancer. (Pen.

(Fn. 1 continued)

such drug, medicine or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation;

"(e) Such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and

"(f) Specimens of the labeling and asvertising proposed to be used for such drug, medicine, compound or device."

Code, § 182, subd. 1; Health & Saf. Code, § 1707.1.) Davis and Turner were convicted of selling laetrile to be used for the alleviation or cure of cancer (Health & Saf. Code, § 1707.1.)

We view the evidence in the light most favorable to the judgments. (People v. Reilly, 3 Cal.3d 421, 425 [90 Cal.Rptr. 417, 475 P.2d 649].) The defendants were involved in a common plan to import, distribute and prescribe laetrile (also referred to as amygdalin or vitamin B-17) to cancer patients. Defendants Turner and Davis were importers and chief suppliers of the drug. Defendants Leslie and Disney worked as the distribution network in various residential areas. Dr. Privitera prescribed amygdalin for cancer victims (or to undercover state agents represented to be cancer victims). Dr. Privitera referred patients to Turner and Davis to buy the amygdalin; Disney referred patients to Dr. Privitera for treatment.

The defendants told the prospective users of the drug that amygdalin was an effective treatment or cure for cancer.

Substantial evidence supports the jury finding of a common plan or agreement to supply and prescribe amygdalin as a cancer cure. Laetrile has not been "approved" by a designated governmental agency.

I

Contentions of the Parties -- Factual and Legal

Dr. Privitera contends that California Health and Safety Code section 1707.1 is an unconstitutional invasion of the cancer victim's right to obtain and use amygdalin in violation of rights guaranteed by the United States Constitution, Amendments I, IV, V, VI, VII, VIII, and XIV, and California Constitution, article I, sections 1, 7, 7(a) and 15. This, he asserts, is an invasion of the patient's right of privacy, his or her right to be left alone in choice of orthodox versus unorthodox treatment of cancer. As a corollary and necessary concommitant of the right of privacy of the patient, Dr. Privitera argues that the constitutional protec-

tion accorded the cancer victim's right to utilize amygdalin in a program of nutritional therapy extends to physicians willing to administer the drug and to persons willing to supply the drug for the cancer victim's use. Argues Dr. Privitera: "The protection of constitutional guarantees of privacy and personal liberty, therefore, extends not only to the patient pursuing a course of nutritional therapy but to the physician who prescribes and administers the therapy and to the person who furnishes the essential components."

Dr. Privitera does not challenge the validity of the general or specific regulatory laws to the extent they prohibit the advertisement of amygdalin as a cure for cancer (Health & Saf. Code, § 1714); or require amygdalin be labeled in accordance with state law and regulations (Health & Saf. Code, § 26463); or impose standards on the manufacturing and packing of amygdalin to insure quality and prevent adulteration or deterioration, or the prohibition of the sale of amygdalin to members of the

general public for the purpose of treating cancer by persons other than licensed physicians (Health & Saf. Code, § 26400 et seq.). (Health & Saf. Code, §§ 1704, 26670, 1707.1, 1709; 17 Cal. Admin. Code, § 10400.1.)

Rather, Dr. Privitera's challenge is directed to those laws, specifically the one of which he is convicted, insofar as they prohibit a duly licensed physician from administering amygdalin to cancer patients and which prohibit its sale to either licensed physicians or persons who have obtained prescriptions from a licensed physician. (Health & Saf. Code, §§ 1700-1721.)

According to Dr. Privitera, this right of choice of medical treatment is a fundamental right of the individual and regulations limiting this right may be justified only by "compelling state interests"; the legislative enactments which seek to regulate or control in the areas of such fundamental rights must be narrowly drawn to protect only the legitimate state interests at stake.

The specific drug here supplied or prescribed is a substance known as

amygdalin, also known as laetrile, and also known as vitamin B-17. Amygdalin is a by-product of apricot pits. The substance has been the subject of widespread public dispute as to its efficacy for the treatment of cancer. Orthodox medicine, as represented by the American Cancer Society, places it in the area of nostrums. Its proponents vary in their claims from that as a cure for cancer or as simply a nutritional aid causing the patient to gain weight, have a better appetite, and a better emotional outlook. It is generally conceded that amygdalin is nontoxic; it does not fall within the general ban of drugs which are toxic, habit forming, addictive, or otherwise distort reality. Coventional medicine regards the "evidence," "proof," of the curative effect of amygdalin as anecdotal in nature and contends the drug has never been established by scientific methodology to have any effect whatsoever upon either the cure or retardation of cancer growth. Despite the pros and cons of the experts in the field of

medicine, and others from nonmedical fields taking side on this issue, cancer victims in large numbers have sought the relief, whatever its nature, which is available from the use of this drug. Where, as in Mexico and in West Germany, the drug is available through doctors and clinics, cancer victims, able to travel, seek out and obtain the treatment.

Dr. Privitera points out that many cancer victims have investigated and evaluated the merits of surgery, radiation therapy or chemotherapy with the aid of competent medical advice and have made the highly personal decision [that] the benefits from such therapy [are] not sufficient to justify the risks which include disfigurement, debilitation, and accelerated death and for this reason have chosen to seek amygdalin as a treatment; other cancer victims have been advised that their condition is hopeless, their case is terminal and as a last resort before certain death, seek amygdalin.

Dr. Privitera contends many concerned cancer victims, competent and responsible

adults, seek and use amygdalin as a food substance to ameliorate the horrifying physical wasting away of the body (cachexia) which accompanies cancer. Thus they seek amygdalin not only for its possible cancer curative benefits, but also for its known nutritional benefits. Cancer victims cannot be certain amygdalin will either cure or control cancer but they believe, based upon the anecdotal, personal experience approach, the drug provides relief from the terrible pain, mental malaise, the emotional depression and weight loss which mark the progression of their disease.

The People assert, contrary to Dr. Privitera's contentions, not a single accredited medical school in the State of California teaches amygdalin might be effective in the controlling or curing of cancer. Further the use of amygdalin as a form of nutritional therapy is officially regarded by the State Department of Health, the California Medical Association, the National Cancer Institute and a great block of practicing physicians, to be of no value

whatsoever in the controlling or curing of cancer.

Dr. Privitera specifically contends section 1707.1 of the Health and Safety Code is unconstitutional. It is a denial of one aspect of individual "liberty" protected by the due process of the Fourteenth Amendment.

The patient, he asserts, has a right of "privacy" or "a guarantee of certain areas or zones of privacy." This is the individual right of independence in making certain kinds of important decisions. The very nature of the relationship, the act to be performed, the decision to be made, precludes unjustified state presence. It is "the right of the individual to be free in action, thought, experience and belief from governmental compulsion." (Kurland, The Private I, University of Chicago Magazine 7, 8, Autumn 1976.) It is that right voiced by Justice Brandeis in his dissent in Olmstead v. United States, 277 U.S. 438, 478 [72 L.Ed. 944, 956, 48 S.Ct. 564, 572, 66 A.L.R. 376] "the right to be let alone", "the right most

valued by civilized men."

Historically this right of privacy was first articulated as a constitutional right in Griswold v. Connecticut, 381 U.S. 479 [14 L.Ed.2d 510, 85 S.Ct. 1678], a decision holding unconstitutional a statute prohibiting the use of contraceptives. However, the recognition of the existence, innate in every human being, of a zone of privacy is older than the Bill of Rights, older than our political parties, older that the state's concern with the nature of treatment to be received by cancer-ridden patients. It is in the nature of man that such right exists.

This principle, now of constitutional dimension, has been embraced by many decisions in a variety of situations.[2/]

2/ In Morris L. Ernst's and Alan U. Schwartz's Privacy: The Right To Be Left Alone (The Mac Millan Co. 1963), the history and broad sweep of this doctrine is documented. Samuel D. Warren and Louis D. Brandeis, in The Right to Privacy (1890), 4 Harvard Law Review 193, state: " . . . it has been found necessary from time to time to define anew the exact nature and extent of such protection."

(See In re Lifschutz, 2 Cal.3d 415, 432, fn. 12 [85 Cal.Rptr. 829, 467 P.2d 557, 44 A.L.R.3d 1], and Roe v. Wade, 410 U.S. 113, 151-153 [35 L.Ed.2d 147, 175-177, 93 S.Ct. 705, 726].) This concept, when placed in the doctor-patient relationship is the "right to decide independently, with the advice of his physician, to acquire and to use needed medication." (Whalen v. Roe, 429 U.S. 589, 603 [51 L.Ed.2d 64, 75, 97 S.Ct. 869, 876, 878]; Doe v. Bolton, 410 U.S. 179, 197 [35 L.Ed.2d 201, 215-216, 93 S.Ct. 739, 750].) In re Lifschutz, supra, 2 Cal.3d 415, 431, 432, makes this profound insight concerning Griswold: "Indeed, the decision's concern for valued aspects of individual privacy may ultimately aid in protecting man from the dehumanization of an everencroaching technological environment."

The People concede, as they must, the fact, the existence of this expanding and as yet judicially unmeasured concept of individual privacy. However, they contend the State of California has the broad power to establish and enforce

standards of conduct within its borders ralative to health. This is a vital aspect of its police power. Within its ambit is the authority of the state to regulate the delivery of health services. (Barsky v. Board of Regents, 347 U.S. 442, 449 [98 L.Ed. 829, 74 S.Ct. 650, 654]; People v. Nunn, 46 Cal.2d 460, 469 [296 P.2d 813].)

This broad premise authorizes the invasion of the doctor-patient zone of privacy by the state to prohibit the doctor prescribing certain species of drugs. (Blinder v. Division of Narcotic Enforcement, 25 Cal.App.3d 174 [101 Cal.Rptr. 635].) The People point to Whalen v. Roe, supra, 429 U.S. 589, 603, fn. 30 [51 L.Ed.2d 64, 75, 97 S.Ct. 869, 878], and Paris Adult Theatre I v. Slaton, 413 U.S. 49, 65, 67 [37 L.Ed.2d 446, 461-463, 93 S.Ct. 2628], in support of this broad position.

The People concede any exercise of police power, depends in the first instance upon an articulated public interest in the activity to be regulated and second, the means used must be rea-

sonably necessary for the accomplishment of that public purpose. (Goldblatt v. Hempstead, 369 U.S. 590, 594, 595 [8 L.Ed.2d 130, 133-135, 82 S.Ct. 987,990].)

At the heart of the People's defense of Health and Safety Code section 1707.1 is the premise, Legislature declared,[3/] that

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3/ Health and Safety Code section 1700 provides:

"The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicates that approximately 16 percent of the total deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom.

"Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various persons in this State have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, which representations are

(Fn. 3 continued.)

early and accurate diagnosis of cancer materially reduces the likelihood of death, prolongs useful life; where false or misleading representations are made to the public, large numbers rely upon

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(Fn. 3 continued.)

misleading to the public, with the result that large numbers of the public, relying on such representations, needlessly die of cancer, and substantial amounts of the savings of individuals and families relying on such representations are needlessly wasted.

"It is, therefore, in the public interest that the public be afforded full and accurate knowledge as to the facilities and methods for the diagnosis, treatment, and cure of cancer available in this State and that to that end there be provided means for testing and investigating the value or lack thereof of alleged cancer remedies, devices, drugs, or compounds, and informing the public of the facts found, and protecting the public from misrepresentation in such matters.

"The importance of continuing scientific research to determine the cause or cure of cancer is recognized, and the department shall administer this chapter with due regard for the importance of bona fide scientific research and the clinical testing in hospitals, clinics, or similar institutions of new drugs or compounds."

such falsities, and needlessly die of cancer.

The People contend the California Legislature in enacting the statutory scheme made this implicit finding: Ineffective cancer remedies are more hazardous to the patient than the state sanctioned alternatives. (Health & Saf. Code, § 1700.)

Concerning the efficacy of amygdalin, this court, this opinion, does not enter that fray. The effectiveness of amygdalin as a cure for cancer or as a nutritional aid with general health giving benefits, is not, as a matter of law, an issue when the charge is a violation of Health and Safety Code section 1707.1. The issue here is human liberty. Can the informed cancer-ridden patient be limited in choice of treatment received from a state licensed physician to "state sanctioned alternatives"?[4/] To resolve these contra-poised contentions we must carefully analyze the nature of the right protected.

4/ People v. Privitera, 55 Cal.App.3d Supp. 39 [128 Cal.Rptr. 151].

II

The Patient's Right to Privacy

The challenge of Dr. Privitera to Health and Safety Code section 1707.1 resolves itself, upon analysis, into two separate and distinct areas of claimed constitutional rights; there is the right of privacy of the patient to choose or reject his or her own treatment, orthodox or unorthodox, approved or unapproved by the state. The second contention is bifaceted: Dr. Privitera asserts (1) a derivative right -- equal in stature to that of his patient, and (2) the doctor's independent right to practice medicine generally and to prescribe medicine, use procedures, without unreasonable government restrictions.

We examine first the right of the patient and determine this right is of such fundamental nature its free exercise may be impinged upon or forbidden only by such state interest as may be a "compelling interest."

The "fundamental" nature of this right derives from its source. It flows from

the very nature of man. Justice Brandeis in Olmstead v. United States, supra, 277 U.S. 438, 478 [72 L.Ed. 944, 956, 48 S.Ct. 564, 572], stated: "The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone -- the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation . . . ." (Italics added.)

Judge Cardozo in Schloendorff v. Society of New York Hospital, 211 N.Y. 125 [105 N.E. 92, at page 93] stated: "Every human being of adult years and

sound mind has a right to determine what shall be done with his own body; . . . ."

The right to control one's own body is not restricted to the wise; it includes the "foolish" refusal of medical treatment. Nor is this right limited in its recognition to any single segment of the political, economic, or social thought spectrum. In commenting upon Justice Brandeis' most valued of rights, that right to be left alone, now Chief Justice Burger, in his dissent in Application of President & Directors of Georgetown Col. 331 F.2d 1010, at page 1017, stated: "Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to sensible beliefs, valid thoughts, reasonable emotions, or well-founded sensations. I suggest he intended to include a great many foolish, unreasonable and even absurd ideas which do not conform, such as refusing medical treatment even at great risk."

Without specific reference to a constitutional basis, the right to choose what

may be a suicidal medical course has been upheld. In Erickson v. Dilgard, 44 Misc. 2d 27 [252 N.Y.S.2d 705, 706] a New York court sustained the unwilling Jehovah's Witness' objection to a needed blood transfusion despite risk of death. The court there said at page 706: ". . . it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."

For analogy we look to the very heart of this right of choice of medical procedures, the right to beget or not to beget a child. In the case of Griswold v. Connecticut, supra, 381 U.S. 479 the Supreme Court held unconstitutional a Connecticut statute prohibiting the use of contraceptives. Following Griswold a series of United States Supreme Court cases have attempted to ascertain the boundaries of this aspect of privacy. The outer limits have not yet been determined. However, it is made clear by

decision that unjustified government interference with personal decisions ". . . relating to marriage, Loving v. Virginia, 388 U.S. 1, 12 (1967); procreation, Skinner v. Oklahoma, 316 U.S. 535, 541-542 (1942); contraception, Eisenstadt v. Baird, 405 U.S. at 453-454 id., at 460, 463-465 (White, J., concurring in result); family relationships, Prince v. Massachusetts, 321 U.S. 158, 166 (1944); and child rearing and education, Pierce v. Society of Sisters, 268 U.S. 510, 535 (1925), Meyer v. Nebraska, supra" (Roe v. Wade, supra, 410 U.S. 113, 152-153 [35 L.Ed.2d 147, 177, 93 S.Ct. 705, 726]) violate this concept.

Roe v. Wade, supra, 410 U.S. 113 dealt specifically with the rights to determine one's own medical treatment. The United States Supreme Court held that the mother's constitutional right of privacy was broad enough to encompass her decision whether to terminate her pregnancy before the end of the first trimester of pregnancy. Said the court at page 163 [35 L.Ed.2d at p. 182]: "With respect

to the State's important and legitimate interest in the health of the mother the 'compelling' point, in light of present medical knowledge, is at approximately the end of the first trimester." (Roe v. Wade, supra, 410 U.S. 113, 163 [35 L.Ed. 2d 147, 182, 93 S.Ct. 705, 731].)

In the companion case, Doe v. Bolton, supra, 410 U.S. 179 the United States Supreme Court held the statutes requiring abortions to be conducted in hospitals, or accredited hospitals, requiring the interposition of a hospital abortion committee and thus limiting abortions to those circumstances was unconstitutional. In vindicating the woman's right of choice of medical care, the Supreme Court stated: "The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." (Doe v. Bolton, supra, 410 U.S. 179, 197 [35 L.Ed.2d 201, 216, 93 S.Ct. 739, 750].)

To support its conclusion, the Supreme

Court examined the role of the licensed physician, saying: "If a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice. The attending physician will know when a consultation is advisable -- the doubtful situation, the need for assurance when the medical decision is a delicate one, and the like. Physicians have followed this routine historically and know its usefulness and benefit for all concerned. It is still true today that '[r]eliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he [the physician] possesses the requisite qualifications.' Dent v. West Virginia, 129 U.S. 114, 122-123 (1889). See United States v. Vuitch, 402 U.S. at 71." (Doe v. Bolton,

supra, 410 U.S. 179, 199-200 [35 L.Ed.2d 201, 217, 93 S.Ct. 739, 751].)

In Whalen v. Roe, supra, 429 U.S. 589, the United States Supreme Court considered the New York statutory requirements with respect to prescriptions for "dangerous, legitimate" drugs. The requirement in question was that of notification. The court balanced the invasion of the zone of privacy against the public's right involved and concluded that with respect to the particular type of drugs involved the statutes were a reasonable exercise of the state's broad police power. In so holding the court discussed the right of an individual to choice of treatment saying: "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication. . . . Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient." (Whalen v. Roe, supra, 429 U.S. 589, 603 [51 L.Ed.2d 64, 75-76, 97 S.Ct. 869, 878].)

Concerning the doctor's "right to practice" Whalen points out: "The appellee doctors argue separately that the statute impairs their right to practice medicine free of unwarranted state interference. If the doctors' claim has any reference to the impact of the 1972 statute on their own procedures, it is clearly frivolous. For even the prior statute required the doctor to prepare a written prescription identifying the name and address of the patient and the dosage of the prescribed drug. To the extent that their claim has reference to the possibility that the patients' concern about disclosure may induce them to refuse needed medication, the doctors' claim is derivative from, and therefore no stronger than, the patients'. Our rejection of their claim therefore disposes of the doctors' as well." (Italics added; Whalen v. Roe, supra, 429 U.S. 589, 604 [51 L.Ed.2d 64, 76, 97 S.Ct. 869, 879].)

Carey v. Populations Services Intern., ____U.S.____ [52 L.Ed.2d 675, 97 S.Ct. 2010], examines the question involving

the availability of contraceptives to minors. The Supreme Court held the right to privacy in matters affecting procreation extends to minors as well as adults.

The California Supreme Court has set forth as a "postulate" or "axiomatic" the right to choose one's own "lawful" treatment. In Cobbs v. Grant, 8 Cal.3d 229, at page 242 [104 Cal.Rptr. 505, 502 P.2d 1], the court, in determining the duty of the physician to secure the informed consent of the patient to treatment, said: "Preliminarily we employ several postulates. . . . The second is that a person of adult years and in sound mind has the right, in exercise of control over his own body, to determine whether or not to submit to lawful medical treatment."

Aden v. Younger, 57 Cal.App. 3d 662 [129 Cal.Rptr. 535], held unconstitutional the provisions of Welfare and Institutions Code section 5326.4 requiring substantive review by a mecial committee of a voluntary, competent patient's consent to choice of electroshock treatment. It was an unjustified

infringment of the patient's right to privacy. This court stated at page 684:

"Where informed consent is adequately insured, there is no justification for infringing upon the patient's right to privacy in selecting and consenting to the treatment. The state has varied interests which are served by the regulation of ECT, but these interests are not served where the patient and his physician are the best judges of the patient's health, safety and welfare.

". . . Any possible need which exists for the voluntary and competent patient cannot prevail in the face of the serious infringement to the patient's right to privacy as guaranteed by Roe v. Wade, supra, 410 U.S. 113 and Doe v. Bolton, supra, 410 U.S. 179." (Aden v. Younger, supra, 57 Cal.App.3d 662, 684.)

This right of choice-of-medical-treatment concept reached its quintessence in the Matter of Quinlan, 70 N.J. 10 [355 A.2d 674]. The New Jersey Supreme Court was called upon to determine whether the father, as guardian of

Karen Quinlan, a 21-year-old girl existing in a "persistent vegetative state," could be authorized to discontinue the extraordinary procedures sustaining the daughter's vital processes. The first question was: Did the comatose Karen Quinlan or her father have a right of choice to choose death or life? And secondly, could the father, through the court guardianship procedures, be authorized on her behalf to make such a choice. The court authorized, through the father-guardian, the withdrawal of the life support processes. The right of privacy inherent in the exceptional circumstances of that case authorized the rejection of the life support systems. Reasoned the court: "The claimed interests of the State in this case are essentially the preservation and sanctity of human life and defense of the right of the physician to administer medical treatment according to his best judgment. In this case the doctors say that removing Karen from the respirator will conflict with their professional judgment." (Matter of Quinlan, supra, 70 N.J. 10

[355 A.2d 647, 663].)

Yet, the court affirmed Karen's right to choice, had she been competent to assert it, and authorized the father to exercise it on her behalf: ". . . there would be no criminal homicide in the circumstances of this case. . . . even if it were to be regarded as homicide, it would not be unlawful." (Matter of Quinlan, supra, 70 N.J. 10 [355 A.2d 647, 669-670].) Concerning the interests of the state in preservation of human health and life the court said: "We have no hesitancy in deciding, in the instant diametrically opposite case, that no external compelling interest of the State could compel Karen to endure the unendurable, ..." (Matter of Quinlan, supra, 70 N.J. 10 [355 A.2d 647, 663].)

III

The Doctor's Zone of Privacy

Dr. Privitera asserts a separate and distinct constitutionally protected right -- a zone of privacy -- to prescribe, to treat patients whether in the

orthodox mode -- free from unjustified state interference.

Whalen v. Roe, supra, 429 U.S. 589, accepts as a premise the existence of the right of the individual patient to choose independently with the advice of his physician to use or not to use a particular medication. Said the Supreme Court at page 603 [51 L.Ed.2d at p. 75]: "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication." However, with respect to the doctor's right to freedom to treat, to minister to the sick, in Whalen v. Roe, supra, 429 U.S. 589, we have heretofore noted the Supreme Court's determination the "doctors' claim is derivative from, and therefore no stronger than, the patients'."

Doe v. Bolton, supra, 410 U.S. 179, however, speaks specifically of the doctor's right to administer medical care. Bolton involved a constitutionally defective statute requiring the consent of two state licensed physicians other

than the patient's own doctor before an abortion could be performed as well as advance approval of three members of the hospital staff where the abortion was to be performed. Concerning this statute the Supreme Court said: "The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview." (Doe v. Bolton, supra, 410 U.S. 179, 197 [35 L.Ed.2d 201, 216, 93 S.Ct. 739 750]; italics added.)

Dr. Privitera additionally asserts an independent right to treat, not derived from or measured by his patient's right of choice, without first obtaining approval of the procedure or drug prescribed from a governmental board. He argues Health and Safety Code section 1707.1 invades this right. Again, as in the right of the patient, the doctor's asserted right must be first examined to determine its nature and thereby select the test, the degree of scrutiny to which the state interference will be

put. The right found must be balanced against the state -- the public interest protected.

Dr. Privitera's right, in relation to the patient, has been viewed traditionally as a species of economic interest rather than as "fundamental" akin to the privacy right. If a rational basis was found to support an encroachment, the statute was sustained.

While a dispassionate reading of the physician's licensing requirements raises some question concerning the total rationality of the licensing scheme, such standards are generally upheld as reasonable and necessary means of protecting the public health.

The more recent cases hint at the more profound right in the doctor. It is postulated: There exists in the doctor licensed to practice medicine a right, constitutional in nature, as yet illdefined, to treat and to treat by unorthodox modalities -- as yet unapproved by the state board -- an informed consenting patient.

Doe v. Bolton, supra, 410 U.S. 179,

200 [35 L.Ed.2d 201, 217, 93 S.Ct. 739, 751], states if a physician is licensed by the state he is recognized by the state as capable of expressing acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are remedies available and "reliance must be placed on the assurance given by his license . . . that he possesses the requisite qualifications."

Roe v. Wade, supra, 410 U.S. 113, 163 [35 L.Ed.2d 147, 183, 93 S.Ct. 705, 732], states concerning the termination of pregnancy during the first trimester: ". . . the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that in his medical judgment, the patient's pregnancy should be terminated." (Italics added.)

Reason based on history, experience, supports the doctor's premise. To require prior state approval before advising -- prescribing-administering -- a new treatment modality for an informed consenting patient is to suppress in-

novation by the person best qualified to make medical progress. The treating doctor, the clinician, is at the cutting edge of medical knowledge.

To require the doctor to use only orthodox "state sanctioned" methods of treatment under threat of criminal penalty for variance is to invite a repetition in California of the Soviet experience with "Lysenkoism."5/ The mention of a requirement that licensed doctors must prescribe, treat, within

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5/ Soviet geneticist T.D. Lysenko, controversial dictator of "communistic" biology during the Stalin period, stultified the science of genetics in the U.S.S.R. for at least a generation. He imposed the "state sanctioned alternative," the curious idea that environmentally acquired characteristics of an organism could be transmitted to the offspring through inheritance. Thus, the Stalinist concept of ideological conformity politically implanted in genetics paralyzed this important branch of Soviet science.

"state sanctioned alternatives" raises the spector of medical stagnation at best, statism, paternalistic Big Brother at worst. It is by the alternatives to orthodoxy that medical progress has been made. A free, progressive society has an enormous stake in recognizing and protecting this right of the physician.6/

6/ Lest the reader suspect these conclusions are alarmist, without relevance to here and now, reference is made to Drug Regulation and Innovation -- Empirical Evidence and Policy Options, by Henry G. Grabowski (1976). This is a summary of studies made -- cost versus benefit analysis of the effects of the 1962 amendment which clothed the Federal Drug Administration with the authority to test new drugs for their "effectiveness" before permitting general prescription and use.

One study surveyed was that by Sam Peltzman. He researched the effect of the 1962 amendment on drug innovation: "In effect, Peltzman's . . . suggests that the rate of innovation in the post-amendment period is more than halved as a result of the 1962 amendments."

Did the Federal Drug Administration effectively weed out ineffective drugs? Peltzman's study shows: ". . . analysis of evaluations by medical experts suggests that the proportion of ineffective drugs has remained roughly the same

(Fn. 6 continued.)

(Fn. 6 continued.)

in the pre-1962 and post-1962 periods. Given that the rate of new drug introductions was more than halved in the post-amendment period, his analysis therefore suggests that a large decline took place in effective drugs." (Italics added.)

The conclusion reached by Professor Grabowski: "A consistent finding is that regulation has had a significant negative effect on the rate of innovation. While each of the individual studies has shortcomings, taken together they would seem to provide considerable support for the hypothesis that regulation has been one of the principal factors responsible for the observed decline in innovation."

Professor Grabowski's study shows: "An indication of the change is the decline in discovery and development of new chemical entities by U.S. firms -- an initial decline from more than one-third of worldwide introductions in the year before the 1962 amendments to the Food, Drug, and Cosmetic Act to less than one-quarter of the total in 1963 . . . and unfortunately, as Professor Grabowski shows, a continued erosion of U.S. leadership thereafter. We have reached the point where innovations based on discoveries by U.S. firms and institutions constitute less than one-sixth of world-wide introductions of new chemical entities . . . and exports of pharmaceuticals as a share of U.S. exports have declined by one-third since the 1950s."

(Fn. 6 continued.)

(Fn. 6 continued.)

Decline in innovation is bad enough yet the public's safety has not been enhanced. Acccrding to Professor Grabowski: "One of the bitter ironies of this situation is that the 1962 amendments were spurred by an alarm over the safety of new drugs -- by the fears created by the thalidomide incident. The irony lies in the fact that the 1972 amendments are keeping off the market new drugs that are safer than the drugs they would replace. Professor William Wardell's study of the lags in the introduction of new drugs in the United States cites, as one example, the five-year delay in the appearance on the U.S. market of a benzodiaze-pine hypnotic. If it had been available in the United States as it was in Great Britain during those five years, Professor Wardell estimates that 1,200 lives would have been saved.5/"

"5/ William M. Wardell, 'Therapeutic Implications of the Drug lag,' Clinical Pharmacology and Therapeutics, vol. 15, no. 1 (January 1974), p. 83." (Henry G. Grabowski, Drug Regulation and Innovation -- Empirical Evidence and Policy Options, p. 2.)"

IV

The Right of Privacy -- Article I, Section 1, of the California Constitution

Thus far we have considered only the specific guarantees of the federal bill of rights and the emanations formed therefrom in concluding fundamental rights are encroached by section 1707.1 However: "'[I]n the area of fundamental civil liberties -- which includes . . . all protections of the California Declaration of Rights -- we sit . . . subject only to the qualification that our interpretations may not restrict the guarantees accorded the national citizenry under the federal charter. In such constitutional adjudication, our first reference is California law and the full panoply of rights Californians have come to expect as their due. Accordingly, decisions of the United States Supreme Court defining fundamental rights are persuasive authority to be afforded respectful consideration, but are to be followed by California courts only when they provide no less indivdual

protection than is guaranteed by California law.'" (Serrano v. Priest, 18 Cal.3d 728, 764, [135 Cal.Rptr. 345, 557 P.2d 929] quoting People v. Longwill, 14 Cal.3d 943, 951, fn. 4 [123 Cal.Rptr. 297, 538 P.2d 753].) (See also People v. Disbrow, 16 Cal.3d 101, 114-115 [127 Cal.Rptr. 360, 545 P.2d 272]; People v. Norman, 14 Cal. 3d 929, 939 [123 Cal.Rptr. 109, 538 P.2d 237]; People v. Brisendine, 13 Cal.3d 528, 548-552 [119 Cal.Rptr. 315, 531 P.2d 1099]; Burrows v. Superior Court, 13 Cal.3d 238, 245-246 [118 Cal.Rptr. 166, 529-P.2d 590]; Mandel v. Hodges, 54 Cal.App.3d 596, 615-617 [127 Cal. Rptr. 244]; State v. Kaluna, 55 Hawaii 361 [520 P.2d 51, 58-59]; Baker v. City of Fairbanks, 471 P.2d 386, 401-402; see generally Note, Project Report: Toward an Activist Role for State Bills of Rights (1973) 8 Harv.Civ.Rights -- Civ. Lib.L.Rev. 271; Falk, Foreword: The State Constitution: A More than "Adequate" Nonfederal Ground (1973) 61 Cal.L.Rev. 273; Note, Rediscovering the California Declaration of Rights (1974) 26 Hastings L.J. 481.)

It is an "incontrovertible conclusion that the California Constitution is, and always has been, a document of independent force. Any other result would contradict not only the most fundamental principles of federalism but also the historic bases of state charters." (People v. Brisendine, supra, 13 Cal.3d 528, 549-550.) We therefore must evaluate the rights infringed by section 1707.1 in light of our own Constitution.

Article I of the state charter is the California Declaration of Rights. Its first section establishes certain inalienable rights: "All people are by nature free and independent and have inalienable rights. Among these are enjoying and defending life and liberty, acquiring, possessing and protecting property, and pursuing and obtaining safety, happiness, and privacy." (Italics added.) "The [federal] Constitution does not explicitly mention any right of privacy." (Roe v. Wade, supra, 410 U.S. 113, 152 [35 L.Ed.2d 147, 176, 93 S.Ct. 705, 726].) Neither did the California Constitution. However, "[i]n November

1972, the voters of California specifically amended article I, section 1 of our state Constitution to include among the various 'inalienable' rights of 'all people' the right of 'privacy.'" (White v. Davis, 13 Cal.3d 757, 773 [120 Cal.Rptr. 94, 533 P.2d 222].)

The California Supreme Court first addressed the significance of the new provision in White v. Davis, supra, 13 Cal. 3d 757, 773-776. In that case the complaint asserted certain government surveillance and data-gathering activities abridged students' and teachers' constitutional right of privacy. In reversing a judment entered upon the sustaining of a general demurrer, the court concluded the activities challenged did fall within the aegis of article I, section 1. The court "intimate[d] no opinion as to the resolution of the ultimate constitutional question after trial" (White v. Davis, supra, 13 Cal.3d 757, 776), and did not purport to sketch "the full contours of the new constitutional provision." (Id., at p. 773.) Nevertheless, we are aided by its observations and analysis.

"The principal objectives of the newly adopted provision are set out in a statement drafted by the proponents of the provision and included in the state's election brochure." (Id., at p. 774.) This statement represents, in essence, the only "legislative history" of the constitutional amendment available (id., at p. 775), and "California decisions have long recognized the propriety of resorting to such election brochure arguments as an aid in construing legislative measures and constitutional amendments adopted pursuant to a vote of the people." (Id., at fn. 11.)

After review of the ballot statements in White v. Davis, supra, 13 Cal.3d 757, the Supreme Court concluded: "Although the general concept of privacy relates, of course, to an enormously broad and diverse field of personal action and belief, the moving force behind the new constitutional provision was a more focussed privacy concern, relating to

the accelerating encroachment on personal freedom and security caused by increased surveillance and data collection activity in contemporary society. The new provision's primary purpose is to afford individuals some measure of protection against this most modern threat to personal privacy." (Id., at pp. 773-774.)

The rights here relied upon by Privitera do not fall within that "more focused privacy concern" of White v. Davis, supra, 13 Cal.3d 757; but rather relates to the "enormously broad and diverse field of personal belief and action." The state here does not seek to surveil or collect data about laetrile users or distributors. It seeks to circumscribe an even more profound compelling interest, that right which is but an "outward manifestation of the inward domain of the consciousness," the right to be left alone.

To find the legislative intent of the people of the State of California in enacting the amendment to article I, section 1, we look to the language of

the election brochure which extends beyond data collection into the broader area of freedom of personal action and belief. The argument in favor of the amendment stated:

"The right of privacy is the right to be left alone. It is a fundamental and compelling interest. It protects our homes, our families, our thoughts, our emotions, our expressions, our personalities, our freedom of communion, and our freedom to associate with the people we choose.

". . . . . .

"The right of privacy is an important American heritage and essential to the fundamental rights guaranteed by the First, Third, Fourt, Fifth and Ninth Amendments to the U.S. Constitution. This right should be abridged only when there is compelling public need." (Italics added.)

The proponents of the amendment further stated (in rebuttal): "The right to privacy is much more than 'unnecessary wordage.' It is fundamental in any free society. Privacy is not now guar-

anteed by our State Constitution. This simple amendment will extend various court decisions on privacy to insure protection of our basic rights." (Italics added.)

This "legislative history" closely parallels the thoughts -- uses the exact words -- of Justice Brandeis in his prescient dissent in Olmstead v. United States, supra, 277 U.S. 438.[7/]

7/ As if he had this case in mind, Brandeis insightfully cautioned: "Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding." (Olmstead v. United States, supra, 277 U.S. 438, 479 [72 L.Ed. 944, 957, 48 S.Ct. 564, 572-573]; Brandeis, J., dissenting.)

Like Brandeis, the people of California have recognized the right to be left alone -- the right to be free in the sphere of private action. It is "fundamental." It protects "our homes, our families, our thoughts, our emotions, our expressions, our personalities . . . ."[8/]

8/ Philosopher John Stuart Mill in his classic work On Liberty (George Routledge 1905) sets forth the philosophic underpinnings for this recently enunciated right to be left alone:

"[T]here is a sphere of action in which society, as distinguished from the individual, has, if any, only an indirect interest; comprehending all that portion of a person's life and conduct which affects only himself, or if it also affects others, only with their free, voluntary, and undeceived consent and participation. When I say only himself, I mean directly, and in the first instance; for whatever affects himself, may affect others through himself; . . . . This, then, is the appropriate region of human liberty. It comprises, first, the inward domain of consciousness; demanding liberty of conscience, in the most comprehensive sense; liberty of thought and feeling; absolute freedom of opinion and sentiment on all subjects, practical or speculative, scientific, moral, or theological. . . . Secondly, the principle requires liberty of tastes and pursuits; of framing the plan of our life to suit

(Fn. 8 continued.)

Based upon the "legislative intent" derived from the express language of the election brochure we conclude a right, of California constitutional dimension, was enacted. This right is not just a shield against threats to personal freedom posed by modern surveillance and data collecting activities. This state-protected right of privacy encompasses a fundamental and compelling interest of the cancer patient to choose or reject his or her own medical treatment on the advice of a licensed medical doctor. This right can be abridged only where there is compelling need.

(Fn. 8 continued)

our own character; of doing as we like, subject to such consequences as may follow: without impediment from our fellow-creatures, so long as what we do does not harm them, even though they should think our conduct foolish, perverse, or wrong . . . .

". . . The only freedom which deserves the name, is that of pursuing our own good in our own way, so long as we do not attempt to deprive others of theirs, or impede their efforts to obtain it. Each is the proper guardian of his own health, whether bodily, or mental and spiritual. Mankind are greater gainers by suffering each

(Fn. 8 continued.)

V

The Nature of the State's Interest

We have established this premise: The patient's and Dr. Privitera's rights of privacy are of such magnitude only a compelling state interest can justify intrusion in the patient-doctor treatment setting. We now consider the strength of that state interest. Does Health and Safety Code section 1707.1 serve a compelling state interest which overrides the rights so found?9/ Indeed, a state has a profound interest in maintaining medical standards and in protecting health, life. This justifies the test-

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(Fn. 8 continued.)

other to live as seems good to themselves, than by compelling each to live as seems good to the rest."

Mill concludes "over himself, over his own body and mind, the individual is sovereign." (Pp. 13-18.)

9/ John Stuart Mill, On Liberty, supra, gives substance to the concept of "compelling state interest" when he asserts: ". . . one very simple principle, as entitled to govern absolutely the dealings of society with the in-

(Fn. 9 continued.)

(Fn. 9 continued.)

dividual in the way of compulsion and control, whether the means used be physical force in the form of legal penalties, or the moral coercion of public opinion. That principle is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinions of others, to do so would be wise, or even right. These are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not for compelling him, or visiting him with any evil in case he do otherwise. To justify that, the conduct from which it is desired to deter him, must be calculated to produce evil to some one else. The only part of the conduct of any one, for which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign."

ing and licensing of doctors and the limits on giving of medical advice by qualified practitioners. The regulation of pharmaceuticals, the licensing requirements for pharmacists and other dispensers of drugs are so authorized. Harm to others is readily forseeable. It is well settled the state has broad police powers in regulating the administering of certain types of drugs by the health professions. (See Robinson v. California, 370 U.S. 660, 664-665 [8 L.Ed.2d 758, 761-762, 82 S.Ct. 1417, 1419-1420]; Minnesota ex rel. Whipple v. Martinson, 256 U.S. 41, 45 [65 L.Ed. 819, 822, 41 S.Ct. 425, 426]; Whalen v. Roe, supra, 429 U.S. 589.)

The cases cited by the People in support of this unquestioned power of the state uniformly involve drugs which are narcotic, habit forming, toxic in nature. For example, as noted in Whalen v. Roe, supra, the New York Legislature had enacted a statutory scheme regulating dangerous, legitimate, drugs such as opium, cocaine, methadone. The state could "prohibit entirely [their] use."

Therefore, the New York statute requiring the doctor to furnish the state with a copy of every prescription for such drugs did not unconstitutionally deprive a person of the right to decide independently with the advice of his physician to acquire or to use needed medication.

In Minnesota ex rel. Whipple v. Martinson, supra, 256 U.S. 41, 45 [65 L.Ed. 819, 822, 41 S.Ct. 425, 426], the Supreme Court reiterated this premise when examining a California statute which regulated morphine stating: "There can be no question of the authority of the state in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs, such as are named in the statute. The right to exercise this power is so manifest in the interest of the public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be successfully called in question."

In Blinder v. Division of Narcotic

Enforcement, supra, 25 Cal.App.3d 174, 181, the authority of the State of California to regulate prescription by a doctor of a narcotic, habit forming, dangerous drug was vindicated. Plaintiff physician sought to prescribe the use of methadone as a necessary and effective method for the treatment of narcotic addiction. The statutes challenged by Dr. Blinder provided for treatment of addicts at certain places and specified periods of time and limited use of methadone in the treatment of other diseases. The court in Blinder held the limitations upon the prescription of methadone for treatment of addicts (Health & Saf. Code, §§ 11391 and 11395) were an appropriate exercise of the police power of the state and did not constitute a denial of equal protection of law or constitute cruel and unusual punishment. Concerning the right of the doctor to practice without state interference, Blinder v. Division of Narcotic Enforcement, supra, 25 Cal.App.3d 174, at page 181, states: "It is well established, moreover, that

although the right to practice medicine, like the right to practice any other profession, is a valuable property right [citation], this right may not be exercised free of reasonable restrictions. 'The state clearly has the power to regulate professions in the interest of public health, safety and welfare.' [Citations.]" It should be noted in Blinder, as in Whipple, as in Robinson, and in Whalen v. Roe, supra, the drugs subject to his broad police power are drugs which are dangerous in the sense that they are narcotic, habit forming, hallucinatory or toxic. Their use or misuse "concerns others." Laetrile is not in this class. It is generally conceded to be a harmless drug. Its alleged evil lies in its "ineffective" treatment of cancer.

The sole case authority submitted for the proposition that the state has the right under its police power to interfere in the doctor-patient relationship where the drug prescribed is amygdalin is People v. Privitera, 55 Cal.App.3d Supp. 39 [128 Cal.Rptr. 151], where the

same Dr. Privitera was charged in the Municipal Court of Los Angeles with a series of misdemeanor violations of section 1707.1 (here charged as the substantive crime, the object of a felony conspiracy). The trial court there sustained defendant's demurrer on the ground section 1707.1 was unconstitutional. The Appellate Division of the Superior Court of Los Angeles County reversed and denied section 1707.1 was overbroad, arbitrary or unreasonable. It was within the constitutional power of the Legislature to prohibit the prescription of amygdalin for cancer treatment. For its authority the appellate division relied upon the cases we cite which warrant state intervention in the doctor-patient area in the control, distribution, use of narcotics and other dangerous drugs.

The Privitera court examined the procedure imposed by the Legislature for the prior administrative determination of whether the drug is recognized as safe and effective. For approval thereof, Privitera relies on the United

States Supreme Court in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 619 [37 L.Ed.2d 207, 217, 93 S.Ct. 2469, 2478], which held in passing upon the safety and efficacy of new drugs, strict scientific standards must be employed and not "anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug." Concerning the problem of whether the scientific and medical authorities are in dispute the appellate division stated: "'Where there is a genuine difference of medical opinion among the experts on the question of whether a drug is generally recognized as safe for the treatment of a particular disease, it must be concluded that the drug is not generally recognized as safe for the use in the treatment of that disease.' (United States v. Article of Drug, etc. (N.D. Ga. 1968) 294 F.Supp. 1307, 1311.)" (People v. Privitera, supra, 55 Cal. App.3d Supp. 39, 51.)

The appellate division examined the right of privacy question but found the state interest to be of such magnitude

as to authorize prohibition of all treatment by physicians of cancer by any modalities other than "state sanctioned alternatives." Said People v. Privitera, supra, 55 Cal.App. 3d Supp. 39, 52: "However, the California Legislature, in enacting the statutory scheme of cancer regulations, made the implicit finding that alleged but ineffective cancer remedies are more hazardous to the patient than the state-sanctioned alternatives. We believe such finding to be reasonable. One desperate for a cure but who seeks to avoid necessary surgery because it is disfiguring, necessary radiation because it is debilitating or necessary chemotherapy because it is toxic, might in his extremity employ substances which are represented to be both harmless and curative. Knowing such propensity of these seriously ill, the Legislature exercised its police power to protect its citizens from the allegedly easier but fallacious cure." (Italics added.)

Reported cases specifically involving the authority, the right, of either the

federal government or state to penalize, prohibit, amygdalin transportation, possession or use are rare. In Rutherford v. United States, 399 F.Supp. 1208, a class action was brought by cancer victims seeking to compel the Federal Drug Administration (FDA) to desist from precluding administration of amygdalin to patients suffering from cancer. By its nonaction, it was contended, the FDA made amygdalin not available. Rutherford sought medical advice in the United States. He was advised of the necessity of abdominal resection, removal of his rectum. He rejected these alternatives and sought laetrile treatment at a medical clinic in Tijuana, Mexico. There he was treated for a period of weeks and was returned as cured. He alleged without the continued use of the amygdalin he faced the prospect of escalation of the carcinoma.

The district court in Rutherford v. United States, supra, found that the FDA, under 21 United States Code section 355, had: ". . . abdicated its duty to

make a clear determination of whether the drug laetrile should or should not be placed in commerce though the drug has been in use for many years and thousands of persons have been treated with it."

The court further found that from the records, testimony and exhibits that: ". . . laetrile is not lethal in any sense of the word. It is not harmful to the human body and when used in proper amounts under proper control and supervision can effect relief from cancer disease to the satisfaction of many who are privileged to use the same." (Rutherford v. United States, supra, 399 F.Supp. 1208, 1212.) In view of this failure of the Federal Drug Administration to act in accordance with the constitutional intent, the court found that Rutherford and others were wholly without means or resources to comply with the provisions of 21 United States Code section 355(b),[10/] further that

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10/ 21 United States Code section 355 provides in part: "(a) No person shall introduce or deliver for introduction into interstate com-

(Fn. 10 continued.)

each of them was denied "the freedom of choice for treatment by laetrile to alleviate or cure their cancer."

Basing its decision upon the Roe v. Wade, supra, 410 U.S. 113, concept of the right of privacy as one of the rights formed by the emanations from the guarantees of the Fifth and Fourteenth Amendments, the court granted the requested injunctive relief.

Rutherford was reviewed sub nomine Stowe v. United States of America (10-12-75) D.C. No. CIV-75-0218-B (10th Cir.).[11/] The court of appeals de-

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(Fn. 10 continued)

merce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug."

11/ Stowe was the original plaintiff in the Rutherford case. He was a cancer patient and died in the pending of the suit. Rutherford and Mrs. Schneider filed further papers in the proceedings. Mrs. Schneider, Rutherford's co-plaintiff, died before the hearing on the preliminary injunction which was issued by the district court.

clined to review the district court's rulings laetrile was an effective treatment for cancer, was not toxic, and the new drug application provision, 21 United States Code section 355(a), was unconstitutional. Rather the court of appeals confined itself to the issue of whether the laetrile was a so-called "new drug" requiring FDA approval. The court of appeals held that the record made before the trial court was not sufficient but concluded the "preliminary injunction granted by the district court in this case should be and the same is upheld." (Italics added.)

After remand to the district court in opinion filed January 4, 1977, it was held: "In view, however, of the complete absence of any good-faith agency record in support of its position in this case, as the record here is not merely incomplete, but virtually nonexistent; and in appreciation of the fact that de-

priving a terminally ill cancer patient of a substance he finds therapeutic, whether such benefit is physical or psychological, creates the very risk that irreparable injury might be sustained."

The district court injunction remains in effect pending remand to the FDA.

In Carnohan v. United States of America, et al., United States District Court, Southern District of California (San Diego), Civil No. 77-0010-GT, plaintiff was a terminal cancer patient. He sought to enjoin the FDA's interference with his importation or interstate transportation of amygdalin for his own consumption.

The court found Carnohan was receiving laetrile in Mexico, and in order to receive the drug he must either choose to live in Mexico or he must commute daily for his treatment. The court weighed its basic authority for the issuance of injunctive relief against the harm to the public that could possibly occur by weakening laws calcu-

lated to prevent victimization of cancer victims by playing on their desperate need. The court observed where a person is terminally ill with cancer and unresponsive to other treatments: ". . . the public harm is considerably reduced. Such a person would not be avoiding other methods of treatment generally [accepted] . . . ." Thereupon the court enjoined the United States Customs Service from interfering in Carnohan's possession and moving in interstate commerce not in excess of a three-month supply of laetrile pending completion by the FDA of its study.

These judically carved out exceptions to the federal prohibition against importation or interstate transportation of amygdalin rest upon an unarticulated premise. No compelling state interest required enforcement of the laetrile ban in the recited circumstances.

VI

Conclusions

We turn now to the final, the pivotal question: Does the imposition of crimi-

nal sanction on the doctor for prescribing amygdalin as a cancer treatment for an informed consenting cancer victim, without first seeking governmental approval of its safety and effectiveness, serve a compelling state interest?

The Legislature has found the state's compelling interest derives from its "interest" in the "effective diagnosis, care, treatment or cure of persons suffering from cancer." (Health & Saf. Code, § 1700.) Further the Legislature found: ". . . accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven . . . reduces the likelihood of death from cancer . . . ." The People argue these are compelling reasons to deny cancer victims the prescriptions by a doctor of as yet an unapproved drug.

Without question, Health and Safety Code section 1707.1 is an attempt at exercise of legislative power in the area of public health to protect the cancer victim. The legislative concern expressed in section 1700 reflects a

well founded and appropriate concern for misleading and false claims of cures for cancer. The section states a truism when it finds: "Various persons in this State have represented and continue to represent themselves as possessing medicines, . . . skills, . . . for the effective diagnosis, treatment, or cure of cancer, which representations are misleading to the public, ..."

However, upon what factual basis duly licensed doctors in the State of California are chargeable, let alone found guilty of the strictures made in the legislative finding is not clear. Why doctors, "recognized by the State as capable of exercising acceptable clinical judgment," are honored by being encompassed within that invidious class of "various persons" who "mislead" the public is obscure. "The . . . suggestion is necessarily somewhat degrading to the conscientious physician, . . . He, perhaps more than anyone else, is knowledgeable in this area of patient care, and he is aware of human frailty, . . . and needs." (Doe v. Bolton, supra, 410

U.S. 1979, 196 [35 L.Ed. 2d 201, 215, 93 S.Ct. 739, 750].)

The legislative finding gives no hint of what rational classification includes medical doctors within the ambit of quacks.

The doctor in California is licensed to practice only after meeting long rigid education, experience qualifications. He is bound by oath to preserve, to prolong, the life of his patient. He is under a legal duty, under threat of malpractice suit, to act in accordance with the generally accepted standards of medical practice in his community in this state. He is required under threat of malpractice to treat only after receiving the informed consent of the patient. (Cobbs v. Grant, supra, 8 Cal.3d 229.) These are the "rational means" society through law has imposed to insure a high standard of performance by the California doctor. It follows after such rigid standards are met, the matter of choice of treatment of the informed consenting patient becomes "a purely medical determination, which is within

a doctor's professional judgment." (Aden v. Younger, supra, 57 Cal.App.3d 662, 677.) "Reliance must be placed upon the assurance given by his license, . . . that he possesses the requisite qualifications." (Dent v. State of West Virginia, 129 U.S. 114, 122-123 [32 L.Ed. 623, 626, 9 S.Ct. 231, 233].)

Limiting this exercise of the doctor's professional judgment on some vague suspicion that "various persons" in this state are engaging in quackery does not follow as a matter of logic.

The premise that "various persons," -- con man, snake oil salesman, -- have made or will make false and misleading representations to the public concerning the diagnosis, treatment and cure of cancer certainly warrants, as rational means, the law which prohibits and makes criminal such acts. Health and Safety Code section 1714 accomplishes this precise purpose. It prohibits a false representation with intent to defraud of any device or substance or treatment as an effective cure for cancer. Dr. Privitera does not contest the appropriate-

ness of Health and Safety Code section 1714 as it does fit the announced legislative purpose.

We conclude the limitation upon the right to prescribe, to treat, of the doctor of section 1707.1 bears no logical relationship to the expressed legislative purpose. A fortiori, if there is a lack of reasonable relationship between the end sought and the means used, then certainly no compelling state purpose is present.12/

12/ Refusing enforcement of Health and Safety Code section 1707.1 is totally compatible with (1) compulsory vaccination, (2) fluoridation of public water supplies, (3) requiring that certain drugs be available to the public on prescription from a licensed doctor, and (4) recognition of a compelling state interest in the health of a prospective mother at approximately the end of the first trimester of pregnancy. (Roe v. Wade, supra, 410 U.S. 113.) Philosopher Mill precisely located the line of demarcation between the individual's control of himself, his own body and mind, and the sovereignty, retained by the state saying "there is a sphere of action in which society, as distinguished from the individual, has if any, only an indirect interest." (John Stuart Mill, On Liberty, supra.) The much quoted Homes' observation that freedom of speech does not

(Fn. 12 continued.)

Dr. Privitera is charged under Health and Safety Code section 1707.1. This statute requires for its breach an intent to prescribe the unauthorized drug or medicine for treatment of cancer. The efficacy of the treatment proposed or medicine prescribed is not an issue under this statute. The truth or veracity of the representations, disclosures, discussions, made in connection with the treatment, by the doctor to the patient are not an issue in a trial of charges made under section 1707.1.

The criminal liability attaches because the doctor in the exercise of his medical judgment has prescribed a drug for treatment of cancer not yet approved under section 505 of the federal Food, Drug and Cosmetic Act or

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(Fn. 12 continued)

encompass the right to shout fire in a crowded theater rests upon the readily recognizable danger to society and thus authorizes state intervention. Roe v. Wade, supra, 410 U.S. 113, is a classic example of a silent application of the Mill reasoning by the United States Supreme Court in delienating the line between the mother's control over her own body and a public interest when there is another life and being.

which has not yet received approval of the state board. Whether the doctor in his best medical judgment believes he has a miracle drug, a food supplement or a hope-giving placebo is not an issue. The governmental agencies have not given approval; therefore the doctor cannot prescribe.

The patient's right to receive medical care, and the doctor's right to administer it are substantially limited not because of some established defect in the medication, some danger to the public if this patient is so treated. The doctor becomes a criminal because the government agency has not given its prior approval to the exercise of his best medical judgment.

The statute must be measured against the legislative purpose of frustrating cancer quacks, and for the promotion of the early effective care, diagnosis and cure of cancer. Instead, the immediate and most direct effect of the prohibition of section 1707.1 is to chill, to prevent, innovative treatment by a licensed doctor, the person or in the

class of persons most likely to make the hoped-for breakthrough against dreaded cancer. How logically this threat to the innovative physician will increase early effective diagnosis and cure of cancer is difficult to perceive.

People v. Privitera, supra, 55 Cal. App.3d Supp. 39 at page 52 of the supplement makes the following remarkable observation concerning that compelling state interest which supports Health and Safety Code section 1707.1:

". . . ineffective cancer remedies are more hazardous to the patient than the state-sanctioned alternatives."
(Italics added.)

The Legislature has not made such an express finding and if such finding should be implied then it denies the patient the exercise of one of his most fundamental rights. He, instead, has the choice of "state sanctioned" treatment by the doctor or no treatment from the doctor at all. Again, if this be the legislative purpose, it misses its mark. Diminishing fraudulent cures,

punishing quackery in cancer treatment, is a laudible objective. The means chosen by the Legislature is bureaucratically predetermined treatment or none, injected into a constitutionally protected area of privacy. This fundamental right of privacy, this right to be left alone, is "older than the Bill of Rights, older than our political systems." It cannot be swept away, denied by the processes of compelled acceptance of "state sanctioned alternatives."

It may be conceded that the dangers of treatment of cancer -- or of any serious and disabling disease -- by nonlicensed purveyor of medical services is fraught with dangers to the public and properly subject to legislative protection. Thus the difficulty with the statute as here applied is that it seeks to remedy the danger (that of a licensed medical doctor prescribing a treatment of a cancer patient without first getting approval of an administrative body) when that danger is not yet shown to exist.

If it be conceded section 1707.1 would theoretically assure some protection to

the public or that unfortunate portion of the public who have cancer but who have not yet heard of the need for early treatment, by prohibiting the use of amygdalin or any unapproved modality by the licensed physician, yet under the law of this state and the United States any individual can possess, use, self-treat, his condition, whatever it may be, by use of amygdalin, to his heart's content without liability.[13/] In effect it turns the whole matter of treatment

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13/ See Ellen S. Hodgson, infra, page 687, footnote 240, pointing out this incongruity. The smuggler of laetrile: ". . . faced a $10,000 fine and five-year prison sentence -- the maximum penalty imposed for smuggling an illegal drug intended for resale in the United States. See 18 U.S.C. § 545 (1970). That only the supplier, not the possessor, of laetrile is subject to criminal prosecution is due to the fact that the drug is not clasified as a 'controlled' substance -- like heroin or marijuana -- the possession of which is illegal. However, because the FDA has not officially recognized the drug as 'safe,' it cannot be brought into the country or transported across state lines."

back to the cancer patient himself if he is unwilling to accept the "state sanctioned alternatives."

We conclude not only is there no compelling reason shown to override the patient's or the doctor's fundamental right of choice in the treatment setting but that the statute when sought to be applied to a licensed medical doctor does not pass the test as a rational means of accomplishment of the announced legislative purpose.

There remains one further concern. The evidence in this case shows without exception the cancer victims, whether People's or defense's witnesses, were knowledgeable persons fully aware of the nature of the "state sanctioned alternatives" before seeking treatment from Dr. Privitera. Many were unwilling to accept the orthodox alternatives; many unwilling to accept the verdict of "terminal." These are not wide-eyed country bumpkins seeking to be conned. The class actions filed against governmental authorities to compell the

availability of the drug in question illustrate the desperate seeking of the cancer victims.[14/] We need cite only one witness as a basis for a composite picture: The patient is a "senior" citizen with diagnosed cancer of the prostate; treatment recommended -- prostate removal and castration; female hormone treatment for the rest of his life. The victim simply refused to accept these alternatives and sought amygdalin treatment.

The nineteen witnesses testifying for Dr. Privitera conveyed a felt imminency of death. One senses a mortal fear of both the disease and the orthodox alternatives. This is a desperate utterly human seeking to avoid the pain and to prolong life. These elements form the unspoken rationale of the Rutherford and Carnohan decisions.

14/ See Ellen L. Hodgson, Restrictions on Unorthodox Health Treatment in California: A Legal and Economic Analysis, 24 UCLA L. Rev. 647, 683, 689, for an excellent and exhaustive review of case and statutory law.

Matter of Quinlan, supra, 70 N.J. 10 [355 A.2d 647, 663], states the premise eloquently: ". . . no external compelling interest of the State could compel Karen to endure the unendurable, only to vegetate a few measurable months with no realistic possibility of returning to any semblance of cognitive or sapient life. We perceive no thread of logic distinguishing between such choice on Karen's part and a similar choice which, under the evidence in this case, could be made by a competent patient terminally ill, riddled by cancer and suffering great pain; such a patient would not be resuscitated or put on a respirator . . . and a fortiori would not be kept against his will on a respirator."

To these nineteen cancer victims the enforcement of Health and Safety Code section 1707.1, the denial to them of medical treatment, albeit unorthodox, albeit unapproved by a state agency, must surely take on a Kafkaesque, a nightmare, quality. No demonstrated public danger, no compelling interest

of the state, warrants an Orwellian intrusion into the most private of zones of privacy.

The state has in the name of protecting the cancer victim criminalized the doctor who is willing to innovate, willing to try an unapproved drug with the consent of his patient. From the terminal patient's viewpoint a new depth of inhumanity is reached by a broad sweep of this law so interpreted. No compelling interest of the state requires Dr. Privitera's 19 cancer patients to endure the unendurable, to die, even forbidden hope.

Health and Safety Code section 1707.1 as here sought to be applied invades the patient's and the doctor's zone of privacy without showing of external compelling state interests in violation of the Fourteenth Amendment to the federal Constitution and articles I, section 1 of the California Constitution."

VII

The Search Warrant Issue

Defendants contend the trial court erred in denying their motion to suppress critical evidence obtained on execution of a telephonic search warrant.

On July 11, 1974, a California magistrate issued the contested telephonic search warrant directing Seth R. Nadel, a special agent with the United States Customs Service, to sign the magistrate's signature to the warrant, which he did.

California Penal Code section 1528(b) provides in pertinent part:

"The magistrate may orally authorize a peace officer to sign the magistrates name on a duplicate original warrant. A duplicate original warrant shall be deemed to be a search warrant for the purposes of this chapter, and it shall be returned to the magistrate as provided for in Section 1537. In such cases, the magistrate shall enter on the face of the original warrant the

exact time of the issuance of the warrant and shall sign and file the original warrant and the duplicate original warrant with the clerk of the court as provided for in Section 1541."

Although a federal agent, Nadel does not qualify as a "peace officer" under California law. (People v. Lacey, 30 Cal.App.3d 170, 175, 105 Cal.Rptr. 72; People v. Yet Ning Yee, 145 Cal.App.2d 513, 516, 302 P.2d 616.) Hence, the search warrant was improperly issued and thus invalid. For,

"[b]ecause the proceeding by a search warrant is a 'drastic one,' whose abuse led to the adoption of the Fourth Amendment itself, legislation regulating the process must be liberally construed in favor of the individual affected. [Citations.] ' . . . [E]very constitutional and statutory requirement must be fully met, including all formalities required by statute, before a valid search warrant may issue.' [Citations.]" (Bowyer v. Superior Court, 37 Cal.App.3d 151, 164,

111, Cal.Rptr. 628, 636-37.)[15/]

Defense counsel failed to raise this contention as a specific ground in their supression motion made before trial.

Defendants contend this court is asked to decide a question of law only. Was Nadel a "peace officer" under the California Penal Code at the time he signed the magistrate's name on the duplicate original warrant? The general rule precludes appellate review on points not raised in the trial court.

15/ See U.S. v. Turner (D.C., Conn.) Crim. No.N-74-124, filed October 5, 1976, where the court granted a motion to suppress the evidence seized under the search warrant here in controversy based upon the identical contention.

The United States Court of Appeal, Second Circuit, reversed the district court's ruling in U.S. v. Turner, supra, Crim.No. N-74-124, June 2, 1977, holding in a federal prosecution, federal law determines whether suppression is authorized. The court commented:

" . . . a violation of the state telephonic search warrant procedures, even if such a violation would result in suppression in the California court, as the district court predicted, would not necessarily require suppression in federal court."

(Fn. 15 Continued.)

Where, however, the newly advanced theory presents only a question of law arising from facts which are undisputed, appellate review is authorized. (Roberts v. Roberts, 241 Cal.App.2d 93, 98, 50 Cal.Rptr. 408 (citations listed); Tyre v. Aetna Life Ins. Co., 54 Cal.2d 399, 405, 6 Cal.Rptr. 13, 353 P.2d 725.)

The facts set forth to obtain the telephonic search warrant show without qualification that Nadel was a United States Customs Service Special Agent. There is no evidence which contradicts or places this fact in issue. The People suggest a speculation--Nadel may have become a California "peace officer" by a cross-deputization process. This argument is pure speculation and contrary to the facts appearing on the face of the document authorizing the search warrant.

(Fn. 15 Continued)

The court then upheld the issuance of the search warrant in that it complied with both rule 41 of the Federal Rules of Criminal Procedure and the Fourth Amendment.

U.S. v. Turner, supra (D.C., Conn.) Crim.No. N-74-124, at page 3 (holding this very search warrant unlawfully issued) said:

"It is clear that, although Special Agent Nadel's duties as a federal officer closely parallel those of a california peace officer, Nadel is not a peace officer under California law."

The evidence Code section 353 requirement of a timely and specific objection is not a universal prohibition against appellate review. The Assembly Judiciary Committee comment following section 353 reads in pertinent part:

"Section 353 is, of course, subject to the constitutional requirement that a judgment must be reversed if an error has resulted in a denial of due process of law. People v. Matteson, 61 Ca.2d 466, 39 Cal.Rptr. 1, 393 P.2d 161 (1964)."

The admission of illegally obtained evidence violates the Fourth Amendment to the United States Constitution. The matter comes to this court as a matter of law of constitutional dimension. We

conclude the search warrant was improperly issued. It was not signed by the issuing judge or a California peace officer on his behalf. The evidence should have been suppressed.

Judgments reversed.

GERALD BROWN, P. J., concurs.

COLOGNE, Associate Justice, dissenting.

I dissent.

The right of a physician to administer drugs and the right of all individuals to import and distribute drugs which have not been approved as effective for the use intended and certified under procedures established by the Legislature are not in my opinion an incident of the constitutionally protected fundamental right of privacy. Moreover, I would take the position that even if there are fundamental rights involved in this case, the state's interest in controlling the distribution of ineffective drugs generally and laetrile particularly is sufficiently compelling to sustain the constitutionality of Health and Safety Code section 1707.1.

The state has broad police powers in regulating the administration of drugs by the health profession (see Robinson v. California (1962) 370 U.S. 660, 664-665, 82 S.Ct. 1417, 1419-1420, 8 L.Ed.

2d 758; Whalen v. Roe (1977) 429 U.S. 589, 97 S.Ct. 869, 878, fn. 30, 51 L. Ed.2 64; Blinder v. Division of Narcotic Enforcement (1972) 25 Cal.App. 3d 174,179-180, 101 Cal.Rptr. 635, 638-39). The authority for the state's regulation under its police power has been well defined in the law.

"'"Police power is the power inherent in a government to enact laws, within constitutional limits, to protect the order, safety, health morals, and general welfare of society."' [Citations.] '"To justify the State in . . . interposing its authority in behalf of the public, it must appear, first, that the interests of the public . . . require such interference; and second, that the means are reasonably necessary for the accomplishment of the purpose, and not unduly oppressive upon individuals."' [Citations.]" (Blinder v. Division of Narcotic Enforcement (1972), supra, 25 Cal.App.3d 174, 179-180, 101 Cal.Rptr. 429 U.S. 589, 97 S.Ct. 869, 875, fn. 20, 51 L.Ed.2d 64.)

In Methodist Hosp. of Sacramento v. Saylor (1971) 5 Cal.3d 685, 691, 97 Cal.Rptr. 1, 5, 488 P.2d 161, 165 we are instructed:

". . . . Unlike the federal Constitution, which is a grant of power to Congress, the California Constitution is a limitation or restriction on the powers of the Legislature. [Citations.] Two important consequences flow from this fact. First, the entire law-making authority of the state, except the people's right of initiative and referendum, is vested in the Legislature, and that body may exercise any and all legislative powers which are not expressly or by necessary implication denied to it by the Constitution. [Citations.] In other words, 'we do not look to the Constitution to determine whether the legislature is authorized to do an act, but only to see if it is prohibited.' [Citation.]

"Secondly, all intendments favor the exercise of the Legislature's plenary authority: 'If there is any doubt as to the Legislature's power to act in any

given case, the doubt should be resolved in favor of the Legislature's action. Such restrictions and limitations [imposed by the Constitution] are to be construed strictly, and are not to be extended to include matters not covered by the language used.' [Citations.] . . ."

Our first inquiry must be whether the state Constitution prohibits the Legislature from adopting Health and Safety Code section 1707.1[1/] The California Constitution neither expressly

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1/ Health and Safety Code section 1707.1 reads as follows: "The sale, offering for sale, holding for sale, delivering, giving away, prescribing of administering of any drug, medicine, compound or device to be used in the diagnosis, treatment, alleviation or cure of cancer is unlawful and prohibited unless (1) an application with respect therto has been approved under Section 505 of the Federal Food, Drug and Cosmetic Act, or (2) there has been approved an application filed with the board setting forth:

"(a) Full reports of investigations which have been made to show whether or not such drug, medicine, compound or device is safe for such use, and whether such drug, medicine, compound or device is effective in such use;

(Fn. 1 continued.)

nor by necessary implication denies to the Legislature the power to enact section 1707.1. The majority asserts article I, section 1, states the right of "privacy," an inalienable right of all the people, includes the right of choice of medical treatment. No constitutional provision expressly provides the right of choice of medical treatment as being reserved to the people. While the general concept of privacy relates, of course, to an enormously

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"(b) A full list of the articles used as components of such drug, medicine, compound or device;

"(c) A full statement of the composition of such drug, medicine, compound or device;

"(d) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug, medicine or compound or in the case of a device, a full statement of its composition, properties and construction and the principle or principles of its operation;

"(e) Such samples of such drug, medicine, compound or device and of the articles used as components of the drug, medicine, compound or device as the board may require; and

(Fn. 1 continued.)

broad and diverse field of personal action and belief, from the ballot pamphlet arguments made with reference to the 1972 election in which the new constitutional provision for "privacy" was adopted, it is apparent the provision's primary purpose is to afford individuals some measure of protection against the threat made to personal privacy by increased surveillance and data collection activity in modern society (White v. Davis (1975) 13 Cal.3d 757, 773-774, 120 Cal.Rptr. 94, 533 P.2d 222). Surveillance and data collection activity bears little resemblance to free choice of one's use of drugs. To stretch the

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(Fn. 1 Continued)

"(f) Specimens of the labeling and advertising proposed to be used for such drug, medicine, compound or device."

privacy right referred to in the California Constitution so as to deny the Legislature the right to proscribe the use of drugs not proven fit for the use intended violates the rule in Methodist Hosp. of Sacramento v. Saylor (1971), supra, 5 Cal.3d 685, 97 Cal.Rptr. 1, 488 P.2d 161, and ignores the legislative purpose intended by adoption of these laws to protect the harassed and often desperate cancer victims (see Health & Saf. Code § 1700). The Legislature has the right to control distribution and use of drugs which are narcotic, habit forming, hallucinatory or toxic (Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 875, 878, 51 L.Ed. 2d 64; People v. Nunn (1956) 46 Cal.2d 460, 469, 296 P.2d 813),[2/] but to

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2/ The Legislature, it must be observed, is the body empowered to decide in the first place whether a particular substance has a deleterious effect, in the second place, whether the substance with that effect should be subject to some form of proscription in the interest of the public health, safety or welfare and, in the third place, what form of form of proscription should apply to various transactions relating to the substance. The

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limit its power to just these kinds of drugs portends a frightening parade of horribles. Protection of public health, safety and welfare demands more.[3/] Rea-

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majority opinion expresses no quarrel with the view and apparently agrees with it insofar as it concerns those substances the Legislature has decided are dangerous because of their narcotic, habit forming, hallucinatory or toxic nature. I do not believe the Legislature's decision-making power as to the "danger" of a substance is limited to those four bases.

3/ Vaccination: Compulsory vaccination statutes represent a significant intrusion upon personal autonomy and yet have been property upheld as not violative of United States constitutional rights (Jacobson v. Massachusetts (1905) 197 U.S. 11, 25 S.Ct. 358, 49 L.Ed. 643). The compelling state interest, of course, is to prevent spread of disease. I would be concerned if the Legislature loses the power to protect that segment of the public.

Flouridation: Fluoridated water is not forced on anyone but obviously people dependent on public water supply must ingest it. The public entity's right to fluoridate public water supplies has been upheld (Minn. State Bd. of Health v. City of Brainerd, Minn. 241 N.W.2d 624).

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sonable assurance the drug is safe and effective before allowing its widespread general public use has been the concern of Congress[4/] as well as the state Leg-

(Fn. 3 Continued)

Antibiotics: It is generally known that widespread use of antibiotics may result in harmful side effects but more importantly can produce new strains of diseases which are immune from the effects of the drug. Limiting one's freedom of choice of such drugs through distribution on prescription only represents a reasonable and proper control.

4/ Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 321, amended in 1962 (P.L. No. 87-781), 76 Stats. 781, codified in 21 U.S.C. §§ 301-392, for example, requires a showing of adequate and well controlled clinical investigations on proof of safety and efficacy, prior to shipment in interstate commerce (§ 355 of the Act). Intended use of a substance, not just the inherent properties or dictionary definition, was held a proper subject of control whether evidenced by labels, promotional material or word of mouth representations. (United States v. Nutrition Service, Inc., D.C.Pa., 227 F.Supp 375, 380).

islature especially of recent years when revelation of some unusual side effects, and birth defects, were noticed after use of certain drugs enjoying substantial public acclaim.[5/] The court should bear in mind that concern.[6/]

5/ See 14 U.S.D. Law Review 378, Government Regulation of Health Care Drugs of Questionable Efficacy. Consider the tragic deformations connected with the use of Thalidomide by pregnant women during the 1960's. See Health and Safety Code section 26000, etc., and particularly section 26670 enacted in 1970.

6/ Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 875, 51 L.Ed.2d 64 reminds us:

". . . State legislation which has some effect on the individual liberty or privacy may not be held unconstitutional simply because a court finds it unnecessary, in whole or in part. ['We are not concerned, however, with the wisdom, need, or appropriateness of the legislation.' Olsen v. Nebraska ex rel. Western Reference and Bond Assn., 313 U.S. 236, 246, 61 S.Ct. 862, 865, 85 L.Ed. 1305.] . . . individual States have broad latitude in experimenting with possible solutions to problems of vital local concern. [Mr. Justice Brandeis' classic statement of the proposition merits reiteration: 'To stay experimentation in things social and economic is a grave

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responsibility. Denial of the right to experiment may be fraught with serious consequences to the Nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens chose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country. This Court has the power to prevent an experiment. We may strike down the statute which embodies it on the ground that, in our opinion, the measure is arbitrary, capricious, or unreasonable. We have power to do this, because the due process clause has been held by the Court applicable to matters of substantive law as well as to matters of procedure. But in the exercise of this high power, we must be ever on our guard, lest we erect our prejudices into legal principles. If we would guide by the light of reason, we must let our minds be bold.' New State Ice Co. v. Liebmann, 285 U.S. 262, 311, 52 S.Ct. 371, 386-387, 76 L.Ed. 747 (dissenting opinion) (footnote omitted).]" (Footnotes connected to text of opinion are shown in brackets.)

To date the United States Supreme Court has denominated only certain activities within the protected realm of the fundamental privacy right[7/] and, since Roe v. Wade (1973) 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147, it has shown a disinclination to expand this right, even in an area closely connected to the matter of choice of medical treatment (Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 876-879, 51 L.Ed.2d 64, see also Planned Parenthood of Cent. Mo. v. Danforth (1976) 428 U.S. 52, 81, 96 S.Ct. 2831, 2846-2847, 49 L.Ed.2d 788, Paul v. Davis (1976) 424 U.S. 693, 713, 96 S.Ct. 1155,

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7/ The United States Supreme Court has characterized its rulings involving the privacy interest in independence in making certain kinds of important decisions as dealing with "matters relating to marriage, procreation, contraception, family relationships, and child rearing and education. In these areas it has been held that there are limitations on the States' power to substantively regulate conduct." (Paul v. Davis (1976) 424 U.S. 693, 713, 96 S.Ct. 1155, 1166, 47 L.Ed.2d 405, see also Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 876-877, fn. 26, 51 L.Ed.2d 64.)

1166-1167, 47 L.Ed.2d 405). In the Whalen, supra, the Court upheld a state statute requiring physicians to report to a state agency the names and addresses of patients for whom the physicians had prescribed certain dangerous drugs. The patients contended, among other things, the statute invaded their constitutionally protected zone of privacy by depriving each of them of the right to decide independently, with the advice of the physician, to acquire and use needed medication. The court upheld the statute, citing cases using ordinary, not "compelling interest" tests for the exercise of the police power (Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 878, fn. 30, 51 L.Ed. 2d 64, see, e.g., Robinson v. California (1962), supra, 370 U.S. 660, 664-665, 82 S.Ct. 1417, 1419-1420, 8 L.Ed.2d 758), and it concluded the impact of the statute on either the reputation or the independence of patients for whom the specified drugs are medically indicated is not sufficient to constitute an invasion of any right or liberty protected

by the Fourteenth Amendment. It held the physicians' claim is derivative from the patients' and must therefore fall along with the rejected patients' claim of protection.

The court in Whalen, supra, did not attach a right of privacy label to the rights there asserted and discussed, nor did it say it was not considering the rights as an incident of the right of privacy. It merely ruled on the basis the statute had minimal impact on "any" protected right or liberty. From the court's delineation of the particular areas of individual concern its past decisions had encompassed within the right of privacy (Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 876-877, fn. 26, 51 L.Ed.2d 64; see fn. 7, p. 788, above, from its citation of cases applying only the standard test for review of the police power [97 S.Ct. 869, 878, fn. 30]) and from its failure to mention the need for the state to show any "compelling" public need for the regulation in question. I cannot view the Whalen, supra, case as

one attaching privacy right status to the patient's right there involved--a right which as the majority opinion suggests, amounts to the same thing as the right of choice of medical treatment.

Roe v. Wade (1973), supra, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed.2d 147, and Doe v. Bolton (1973) 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201, do not deal with a right of choice of treatment. They deal only with the right of a woman to decide whether to terminate her pregnancy without unwarranted state interference (Roe v. Wade (1973), supra, 410 U.S. 113, 155, 93 S.Ct. 705, 727-728, 35 L.Ed.2d 147; Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 879, fn. 33, 51 L.Ed.2d 64). It is an unreasonable extension of logic to attempt to use the cases dealing with

the privacy right of choice to have an abortion, a medically approved procedure when performed during the appropriate time of pregnancy and by a licensed physician, to reach the distinguishable right of choice of the use of drugs which are not proven to be a medically effective treatment of cancer as represented.

In Bowland v. Municipal Court (1976) 18 Cal.3d 479, 134 Cal.Rptr. 630, 556 P.2d 1081, the court was faced with the argument a woman's liberty to choose whomever she wants to assist in the delivery during the birth of her child is a privacy right. Our Supreme Court denied relief to the plaintiffs, midwives charged with practing medicine without a license (Bus & Prof. Code § 2141), saying of their privacy assertions at 18 Cal.3d page 495, 134 Cal. Rptr., at page 638, 556 P.2d at page 1089:

". . . the right of privacy has never been interpreted so broadly as to protect a woman's choice of the manner and circumstances in which her baby is born.

Indeed, Roe, supra [Roe v. Wade (1973) 410 U.S. 113, 152-153, 93 S.Ct. 705, 726-727, 35 L.Ed.2d 147], appears specifically to exclude the right to make such choices from the constitutional privacy right. In Roe, the United States Supreme Court held expressly that the state may proscribe the performance of an abortion at any stage of pregnancy by a person who is not a licensed physician. (Roe, supra, at p. 165, 93 S.Ct. 705, 35 L.Ed.2d at pp. 183-184.) More significantly, the court held that at the point of viability of the fetus, the state's interest in the life of the unborn child supersedes the woman's own privacy right, and at that point (the beginning of the third trimester) abortion may be prohibited except where necessary for the preservation of the mother's life or health. (Roe, supra, at pp. 164-165, 93 S.Ct. 705 [35 L.Ed. 2d at pp. 183-184]; see also People v. Barksdale, supra, 8 Cal.3d 320, at p. 338, 105 Cal.Rptr. 1, 503 P.2d 257.)

"It is true that the Legislature has never attempted to require women to give

birth in a hospital or with a physician in attendance, just as it has not generally sought to compel adults to obtain medical treatment. But the state has a recognized interest in the life and wellbeing of an unborn child. (Roe v. Wade, supra, 410 U.S. 113, at p. 165, 93 S.Ct. 705, 35 L.Ed.2d 147, at pp. 183-184; People v. Barksdale, supra, 8 Cal.3d 320, at p. 335, 105 Cal.Rptr. 1, 503 P.2d 257.) For the same policy reasons for which the Legislature may prohibit the abortion of unborn children who may have reached the point of viability, it may require that those who assist in childbirth have valid licenses. Its interest in regulating the qualifications of those who hold themselves out as childbirth attenders is an equally strong one, for many women must necessarily rely on those with qualifications which they cannot personally verify. Nor is the state's interest in requiring a licensed diminished by the fact that childbirth with assistance, even the assistance of an unlicensed

person, may be safer then self-delivery. The state need not prohibit the most unlikely of circumstances--childbirth without assistance--in order to justify regulating the much more common event--assistance of the mother at childbirth. In the area of public welfare, the Legislature need not attack every social problem at once. (Dandridge v. Williams (1970) 397 U.S. 471, 486-487, 90 S.Ct. 1153, 25 L.Ed.2d 491, 502-503; People v. Barksdale, supra, 8 Cal.3d 320, at p. 338, 105 Cal.Rptr. 1, 503 P.2d 257.). . ." (Bowland v. Municipal Court (1976), supra, 18 Cal.3d 479, 495, 134 Cal.Rptr. 630, 638, 556 P.2d 1081, 1089.)

Thus, the pregnant woman chosing her assistant in giving birth to the child is limited in her choice to the state-licensed physician.

Moreover, the Supreme Court has held a woman seeking an abortion during the first trimester of the pregnancy, the period in which the court found a narrowly drawn state regulation supported by compelling circumstances is the only

type of regulation constitutionally permitted, is nevertheless properly subject to some limitations imposed by the state, namely, that any physician participant be state licensed (Roe v. Wade (1973), supra, 410 U.S. 113, 164-165, 93 S.Ct. 705, 732-733, 35 L.Ed.2d 147).

I would note in passing that some of the defendants here are unlicensed importers and distributors and the effect of the majority opinion would be to pass to them, too, the right to sell drugs not proven to be effective to meet the needs of the patient. They, too would apparently acquire a derivative right to supply. The physician's right, if any he has, is of no greater strength than the patient's (Whalen v. Roe (1977), supra, 429 U.S. 589, 97 S.Ct. 869, 879, fn. 33, 51 L.Ed.2d 64). The patient has no expertise and deals with promoters who similarly have no special medical background. Must we sanction "clinical" experiments even in the absence of a physician? Here, Privitera's presence was required only because the drug required injection. The scheme

presented by the facts of this case was for the doctor to refer his patients to distributors for the drugs and the distributors to refer cancer victims to the doctor to administer the drug, suggesting the patient has a minimal role in the operation from which the rights are derived. In any event, distribution of drugs by untrained and unlicensed persons must fall into a special category subject to state regulation (Bowland v. Municipal Court (1976), supra 18 Cal.3d 479, 134 Cal.Rptr. 630, 556 P.2d 1081).

On the question of reliance on the Quinlan case (Matter of Quinlan, 70 N.J. 10, [1976] 355 A.2d 647), I must disagree with the majority opinion, too, since Quinlan was concerned with a patient's right to reject life support systems, a right to refuse profered medical treatment was not involved in Quinlan where the question involved a right to choose to die by rejecting any treatment at all. Here, by contrast, the patients and the others involved seek medical assistance by use of particular unorthodox procedures which have not been found fit

for the use intended. I cannot view Quinlan as having any persuasive effect in this case.

The right of choice of medical treatment has no similarity to any of the privacy areas including the areas of marriage, procreation, contraception, family relationships, and child rearing and education, so far identified by the courts as subject to regulation only where compelling state interest exists because of the "fundamental" nature of those areas. The right we deal with here is unique. It is fraught with many and variable incidents beyond the influence of an individual's exercise of his right of choice of medical care, for that matter beyond the influence of any society's present ability to act. These variable incidents of the right relate to the nature and extent of the medical condition and to the medical, economic and educational resources available to the person immediately affected by the medical condition. Yet in the case of many cancer patients there are known

medical treatments with proven medical effectiveness which provide in many cases a positive cure. Why is it a fundamental right to have unproven treatment when effective treatment may be available?

My concern with the majority view is not with the proposition we must place great importance upon the right of choice of medical treatment. My concern is that we give it so much importance we deny reason and the best medical judment as the standard for health care. I cannot agree with the majority that Health and Safety Code section 1707.1 bears no logical relationship to its expressed legislative purpose of frustrating cancer quacks and promoting early effective care, diagnosis and cure of cancer.

Preventing the administration of ineffective treatment methods to sick persons, particularly those with a fear-inducing and desperation-producing illness such as cancer, is a reasonable legislative purpose. Taking legislative action to accomplish this purpose promotes the use

of effective treatment methods to the end of the physical and economic well-being of all the people. The legislative action here under consideration, proscribing the administration of other than an effective cancer treatment method, operates to prevent the administration of ineffective cancer treatment methods. Thus, the legislation is reasonably related to a legitimate state objective.

This preventative legislative action naturally tends to enable many persons suffering from the ailment to get well by having effective treatment methods applied at any early stage. There are proven effective treatment methods for many forms of cancer particularly in cases of early detection. The Legislature has been made mindful of the human and economic waste attending a cancer patient's receipt of ineffective treatment and attending the offering of false hope to the frightened or desperate patient. I cannot charge wrongdoing by the manufacturers, distributors and physicians who may profit

from the dispensing of laetrile if they merely provide hope to the terminally ill who have no recognized cure available [8/] but there is a grevious wrong committed when they consciously or unconsciously deny proper treatment to those who could benefit by early effective treatment. Diverting the patient's attention and resources from use of an effective remedy at a time when the cancer might be cured under approved treatment programs is cruel and inhuman. Such a diversion is surely dangerous to the patient, at best giving him a gamble an unproven treatment might be effective and at worst resulting in wasted resources and death. There is also a wrong in taking money from patients for possibly worthless drugs, thereby unduly taxing cancer victims and also depriving them or their families of funds necessary for support.

8/ Making a distinction between the curable and noncurable persons being treated might be an appropriate matter for special consideration by the Legislature (see S.B. 245, 1977 Session of the Cal. State Legislature).

These are legitimate, reasonable objectives for the exercise of the legislative power, promoting early effective cancer treatment and consumer protection. The legislative concern is expressed in the law:

"The effective diagnosis, care, treatment or cure of persons suffering from cancer is of paramount public importance. Vital statistics indicate that approximately 16 percent of the total deaths in the United States annually result from one or another of the forms of cancer. It is established that accurate and early diagnosis of many forms of cancer, followed by prompt application of methods of treatment which are scientifically proven, either materially reduces the likelihood of death from cancer or may materially prolong the useful life of individuals suffering therefrom.

"Despite intensive campaigns of public education, there is a lack of adequate and accurate information among the public with respect to presently proven methods for the diagnosis, treatment, and cure of cancer. Various

persons in this State have represented and continue to represent themselves as possessing medicines, methods, techniques, skills, or devices for the effective diagnosis, treatment, or cure of cancer, which representations are misleading to the public, with the result that large numbers of the public, relying on such representations, needlessly die of cancer and substantial amounts of the savings of individuals and families relying on such representations are needlessly wasted.

"It is, therefore, in the public interest that the public be afforded full and accurate knowledge as to the facilities and methods for the diagnosis, treatment, and cure of cancer available in this State and that to that end there be provided means for testing and investigating the value or lack thereof of alleged cancer remedies, devices, drugs, or compounds, and informing the public of the facts found, and protecting the public from misrepresentation in such matters.

"The importance of continuing scientific research to determine the cause or cure of cancer is recognized, and the department shall administer this chapter with due regard for the importance of bona fide scientific research and the clinical testing in hospitals, clinics, or similar institutions of new drugs or compounds." (Health & Saf. Code § 1700.)

Section 1707.1 reasonably relates to these objectives.

In a case upholding regulations adopted under section 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C., § 355) pertaining to the scientific evidence necessary for a showing of a drug's effectiveness the United States Supreme Court observed the regulations' "strict and demanding standards, barring anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug, are amply justified by the legislative history. The hearings underlying the 1962 Act [adding a showing of <u>effectiveness</u> of a drug as a prerequisite for permissible market-

ing of a new drug] show a marked concern that impressions or belief of physicians, no matter how fervently held, are treacherous." (Weinberger v. Hynson, Westcott and Dunning, Inc. (1973) 412 U.S. 609, 619, 93 S.Ct. 2469, 2478, 37 L.Ed.2d 207). The court in the Hynson case further said:

"But Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labeled in mysterious scientific dress. The standard of 'well-controlled investigations' particularized by the regulations is a protective measure designed to ferret out those drugs for which there is no affirmative, reliable evidence of effectiveness. . . ." (412 U.S. 609, 622, 93 S.Ct. 2469, 2479, 37 L.Ed.2d 207.)

". . . . The 'substantial evidence' requirement reflects the conclusion of Congress, based upon hearings, that clinical impressions of practicing

physicians and poorly controlled experiments do not constitute an adequate basis for establishing efficacy. . . ." (412 U.S. 609, 630, 93 S.Ct. 2469, 2483, 37 L.Ed.2d 207.)

In upholding the regulations it considered, the court in Hynson impliedly also upheld the statute on which the regulations were based, for the regulations could not stand without a valid underlying statute authorizing their adoption. The same concerns of Congress, cited in Hynson, no doubt motivated the California Legislature to enact Health and Safety Code section 1707.1 which, in part, adopts the same federal regulatory scheme of approval ruled on in Hynson, supra.

The majority tells us the effect of the prohibition of Health and Safety Code section 1707.1 is to chill innovative treatment by a licensed doctor. I cannot ignore the conclusion reached by Congress after its hearings that the clinical impressions and beliefs of practicing physicians are "treacherous," are poorly controlled experiments and

do not constitute an adequate basis for establishing efficacy. (Hynson, supra). If we use the method of developing medical knowledge suggested by the majority opinion we discard the scientific approach thus opening the door to experimentation using a variety of disjointed cancer "treatments" of unproven or unprovable value, undocumented for general use and without control mechanisms. Better reasoning calls for an orderly collection of cancer treatment methods of scientifically proven worth before the public is used as the guinea pig. Certainly it is the research scientist, knowledgeable in the field and aware of related studies, who is the one to be given this freedom, not the manufacturer, distributor and general practitioner as the majority would advocate. Unrestricted sale and experimentation is one thing, scientific determination is quite another (see Weinberger v. Hynson, Westcott and Dunning, Inc. (1973), supra, 412 U.S. 609, 618-619, 93 S.Ct. 2469, 2477-2478, 37 L.Ed.2d 207.) The law provides a method of developing such research. The innovative physician is free to take advantage of Health and Safety Code section 1708 which establishes a means of conducting investigations into the safety and therapeutic value of a cancer drug, medicine, compound or device without fear of penalty (see also 21 U.S.C., § 355(i); 17 Cal. Adm. Code § 10401.1).

I am compelled, too, to respond to the majority's position the "rational means" the state has adopted to insure a high standard of performance by the California doctor consist of the physicians' obtaining necessary qualification for a license to practice medicine and his duty, under threat of a malpractice suit, to act in accordance with the generally accepted standards of medical practice in

his community. I agree these are rational methods designed to achieve the desirable end of high medical standards. They are not, however, the only means which we have available for guaranteeing the public well-being. They do not address themselves readily to the specific problem of the prevention of quackery in cancer treatment. There is ample evidence available to show a well-meaning licensed medical practitioner can innocently become an instrument of a drug promotion program without intent to jeopardize the public health and safety. In fact, a licensed medical doctor administering unproven cancer cures which do not work may likely have a more deadly impact on the public health than the nonlicensed promoter. This is so because "the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process . . . . " (Cobbs v. Grant (1972) 8 Cal.3d 229, 242, 104 Cal.Rptr. 505, 513, 502 P.2d

1, 8.) A patient in these circumstances of trust is likely to stay with the physician to the end. When the end is a needless death, an unnecessarily shortened life or a prolonged illness, the remedies of malpractice or license revocation take on a hollow ring to the patient or his heirs. Criminal sanctions provide a strong deterrent to the promotion of such ineffective remedies and physicians have no special right to avoid the additional sanction which the Legislature has imposed. Health and Safety Code section 1707.1 takes such a deterrent approach.

The state's interest in the life and health of a cancer victim, from the onset of the disease, is surely as "important and significant" as its interest in the health of a pregnant woman and her baby after the first trimester of the pregnancy (see Roe v. Wade (1973), supra, 410 U.S. 113, 159, 163, 93 S.Ct. 705, 730-732, 35 L.Ed.2d 147). Both involve the lives of persons. The "compelling" point of this interest in the case of a

cancer victim must be viewed as beginning at least as soon as the time of first detection of the disease, for that is the point of highest likelihood of success from the "application of methods of treatment which are scientifically proven" (Health & Saf. Code § 1700). The danger to the life and health of the cancer victim increases as time passes without the administration of proven treatment methods. Thus, even assuming a "fundamental" right analysis were called for here, the Health and Safety Code section 1707.1 regulation can be sustained by a showing of a compelling state interest in the health and life of a cancer victim from the moment of first detection of the disease. The section, moreover, is drawn in a sufficiently narrow manner to express only the legitimate state interest in the life and health of the cancer victim by promoting the early use of scientifically proven treatment methods and preventing the readily apparent dangers of loss of life and health of these persons due to application of

unproven "remedies." (See Roe v. Wade (1973), supra, 410 U.S. 113, 155, 93 S.Ct. 705, 728, 35 L.Ed.2d 147.)

Viewing the case from the approach required by Methodist Hosp. of Sacramento v. Saylor (1971), supra, 5 Cal. 3d 685, 691, 97 Cal.Rptr. 1, 488 P.2d 161, and testing the statute by the rule summarized in Blinder v. Division of Narcotic Enforcement (1972), supra, 25 Cal.App.3d 174, 179-180, 101 Cal. Rptr. 635, I agree with the conclusion reached by the Appellate Department of the Los Angeles Superior Court in People v. Privitera (1976) 55 Cal.App.3d Supp. 39, 128 Cal.Rptr. 151 (involving the same defendant as in this case), and would uphold the statute as a reasonable exercise of the police power.

Finally, as to the alleged illegal search and seizure asserted by Privitera, People v. Talley (1967) 65 Cal.2d 830, 837, 56 Cal.Rptr. 492, 423 P.2d 564, in a similar search and seizure assertion context, sets forth the rule that a search and seizure issue may not be raised for the first time on appeal.

Privitera's attack on the warrant was not raised below and is in this category. The alleged illegal search is predicated on the fact the telephonic warrant was signed by a federal customs agent for the magistrate, rather than a "peace officer" as required by statute. The investigation here was a joint state and federal operation and it is not uncommon in these cases for the agents to deputize each other. Had the issue been raised below the trial court might have been provided evidence of his authority so we would have a record to support the due issuance of the warrant. A conclusion the officer was not a "peace officer" and the warrant is therefore illegal, is totally speculative. There is reason for the rule set out in Talley, supra, and I believe we should follow it (Auto Equity Sales, Inc. v. Superior Court (1962) 57 Cal.2d 450, 455, 20 Cal.Rptr. 321, 369 P.2d 937, see also People v. Robinson (1965) 62 Cal.2d 889, 894, 44 Cal.Rptr. 762, 402 P.2d 834; People v. McDowell (1972) 27 Cal.App.3d 864, 879, 104 Cal. Rptr. 181).

Supreme Court, U. S.
FILED
OCT 17 1979
MICHAEL RODAK, JR., CLERK

IN THE
Supreme Court of the United States

October Term, 1978

No. 78-1850
No. 79-5049

JAMES ROBERT PRIVITERA, JR.
Petitioner,

v.

THE STATE OF CALIFORNIA,
Respondent.

No. 78-1850

WILLIAM DAVID TURNER, et al.,
Petitioners,

v.

THE STATE OF CALIFORNIA,
Respondent.

No. 79-5049

ON PETITION FOR A WRIT OF CERTIORARI
TO THE SUPREME COURT OF CALIFORNIA

RESPONDENT'S BRIEF IN OPPOSITION

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TOPICAL INDEX

	Pages
JURISDICTION	2
QUESTION PRESENTED	2
STATEMENT OF THE CASE	2 - 4
STATEMENT OF FACTS	4
REASON FOR DENYING THE PETITION FOR A WRIT OF CERTIORARI	
THE CALIFORNIA SUPREME COURT'S DECISION THAT PREMARKET REQUIREMENTS OF DEMONSTRATED SAFETY AND EFFICACY FOR ANY CANCER TREATMENT DO NOT IMPERMISSIBLY INVADE AN INDIVIDUAL'S RIGHT OF PRIVACY, IS SQUARELY IN ACCORD WITH THE HOLDINGS OF THIS COURT	5 - 13
CONCLUSION	13

TABLE OF AUTHORITIES

	Pages
CASES	
Carey v. Population Services Int. (1977) 431 U.S. 678	6
Ciba Corp. v. Weinberger (1973) 412 U.S. 640	11
Doe v. Bolton (1973) 410 U.S. 179	6,7,8
Douglas v. Noble (1923) 271 U.S. 165	9
Eisenstadt v. Baird (1972) 405 U.S. 438	6
England v. La. State Board of Medical Examiners (E.D.La. 1965) 246 F.Supp. 993	9
Garcia v. Texas State Board of Medical Examiners (W.D.Tex. 1974) 384 F.Supp. 434	9
Griswold v. Connecticut (1965) 381 U.S. 479	6
NLRB v. Sears, Roebuck & Co. (1975) 421 U.S. 132	13
People v. Privitera (1979) 23 Cal.3d 697 (153 Cal.Rptr. 431, 591 P.2d 919)	11
Planned Parenthood v. Danforth (1976) 428 U.S. 52	5,6,10
Robinson v. California (1962) 370 U.S. 660	9
Roe v. Wade (1973) 410 U.S. 113	passim

TABLE OF AUTHORITIES
(Continued)

	Pages
CASES	
Weinberger v. Hynson, Westcott & Dunning (1973) 412 U.S. 609	11
Whipple v. Martinson (1921) 256 U.S. 41	9
United States v. Dotterweich (1943) 320 U.S. 277	12
United States v. Park (1975) 421 U.S. 658	12
United States v. Rutherford (June 18, 1979) 99 S.Ct. 2470, ___ U.S. ___	11
United States v. 7 Jugs, etc. of Dr. Salsbury's Rakos (D.Minn. 1944) 53 F.Supp. 746	12
Whalen v. Roe (1977) 429 U.S. 589	5
STATUTES	
21 U.S.C. 355(d)	5
California Health and Safety Code	
§ 1707.1	5,6,13
§ 1707.1, subds. (a)-(f)	5

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No. 78-1850
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THE STATE OF CALIFORNIA,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE SUPREME COURT OF CALIFORNIA

RESPONDENT'S BRIEF IN OPPOSITION

The respondent, the State of California, respectfully requests that this Court deny the petition for a writ of certiorari, seeking review of the California Supreme Court's opinion in this case. That opinion is reported at 23 Cal.3d 697 (153 Cal.Rptr. 431, 591 P.2d 919).

JURISDICTION

This Court has jurisdiction to consider this case pursuant to 28 U.S.C. 1257, subdivision 3.

QUESTION PRESENTED

Does California Health and Safety Code section 1707.1, which prohibits the sale, prescription or administration of an untested and unproven cancer treatment, infringe on the right of privacy protected by the United States Constitution?

STATEMENT OF THE CASE

On October 3, 1974, the San Diego County, California, Grand Jury returned a three count indictment against petitioners, as well as one Eli Von Pinoci. In count I, all were charged with conspiracy to violate California Health and Safety Code section 1707.1, the sale of drugs, compounds or devices for the alleviation or cure of cancer, all in violation of California Penal Code section 182, subdivision (1). Fifty-two overt acts were alleged against the various defendants. In count II petitioner Davis was charged with unlawfully selling a drug and compound to be used in the treatment, alleviation and cure of cancer in violation of California Health and Safety Code section 1707.1. In count III, petitioners Turner and Davis were also charged with a violation of California Health and Safety Code section 1707.1. (1 CT 1-7.)

On October 8, 1974, petitioners Davis and Turner were arraigned in the San Diego County Superior Court. Petitioner Disney was arraigned on October 11, 1974,

while petitioner Privitera was arraigned on October 22, 1974. All petitioners entered pleas of not guilty to the charges. (IV CT 666-667, 669-671.)

Petitioners' demurrer to the indictment was heard on November 21 and 22, 1974, and denied by written opinion on January 2, 1975. (II CT 244-259; IV CT 683-687, 693.) A request for a rehearing on the demurrer was denied on January 23, 1975. (IV CT 704.)

On March 7, 10 and 11, 1975, petitioners' pretrial motions pursuant to Penal Code sections 995 and 1538.5 were heard by the court. (IV CT 710-713.) On March 18, 1975, the motions were denied. (IV CT 714.)

Petitioner Disney filed a motion to dismiss the indictment on the grounds of violation of a prior plea bargain and double jeopardy. (II CT 256; IV CT 714.) The motion was heard on April 15, 1975, and denied on June 12, 1975. (IV CT 732, 735.)

Petitioners Turner, Davis and Disney filed motions for severance and separate trials on July 8, 1975. (IV CT 738-740.) The motions were denied. (IV CT 742.)

Petitioners' jury trial began on July 29, 1975. (IV CT 743.) The prosecution's motion to dismiss count II as to petitioner Davis was granted by the trial court on October 9, 1975. (VII RT 372-376; IV CT 783.) On December 16, 1975, the jury returned its verdicts finding all of the petitioners guilty as charged in count I (conspiracy) and finding petitioners Turner and Davis guilty as charged in count III (sale of drug and compound to be used in the alleviation and cure of cancer). (II CT 417-423; IV CT 810-811.)

Petitioners' motion for a new trial was denied. (IV CT 814.) On February 2, 1976, petitioners were sentenced. Each petitioner was granted probation on certain terms and conditions. (III CT 588-592; IV CT 816.)

Each petitioner filed a timely notice of appeal. (III CT 593, 595, 611, 614, 665.) On November 10, 1977, the Court of Appeal, in a published opinion, reversed all of the convictions. However, on March 15, 1979, the California Supreme Court upheld the convictions of petitioners. Petitioners' petition for a rehearing was denied on April 12, 1979.

STATEMENT OF FACTS

The California Supreme Court aptly summarized the voluminous evidence presented at petitioners' trial.

> ". . . the evidence amply supports the jury's conclusion that defendants were involved in a common plan to import, prescribe, sell and distribute laetrile (also referred to as amygdalin or vitamin B-17) to cancer patients. Dr. Privitera prescribed laetrile for cancer patients and referred his patients to Turner and Disney as suppliers of laetrile. Disney referred patients to Dr. Privitera for treatment. Leslie and Disney worked as distributors in various residential areas. Defendants told prospective users that laetrile is an effective treatment or cure for cancer. Laetrile has not been approved for that purpose by one of the designated governmental agencies." (People v. Privitera, supra, at p. 701 [153 Cal.Rptr. at p. 433, 591 P.2d at p. 921].)

REASON FOR DENYING THE PETITION FOR A WRIT OF CERTIORARI

THE CALIFORNIA SUPREME COURT'S DECISION THAT PREMARKET REQUIREMENTS OF DEMONSTRATED SAFETY AND EFFICACY FOR ANY CANCER TREATMENT DO NOT IMPERMISSIBLY INVADE AN INDIVIDUAL'S RIGHT OF PRIVACY, IS SQUARELY IN ACCORD WITH THE HOLDINGS OF THIS COURT

California Health and Safety Code section 1707.1 prohibits anyone from selling, delivering, giving away or prescribing any drug, medicine, compound or device for the diagnosis, treatment, alleviation or cure of cancer unless the item involved has been approved under either section 505 of the Federal Food, Drug and Cosmetic Act or by the State of California. In order to obtain approval for the item in question, the basic showing which must be made according to rigorous scientific proof, is that the item is both safe and effective for the use intended. (Calif. Health & Safe. Code, § 1707.1, subds. (a)-(f); 21 U.S.C. 355(d).) Relying on three decisions of this Court, Planned Parenthood v. Danforth (1976) 428 U.S. 52, Roe v. Wade (1973) 410 U.S. 113, and Whalen v. Roe (1977) 429 U.S. 589, the California Supreme Court ruled that Health and Safety Code section 1707.1 bore a reasonable relationship to the legitimate state interest in the health and safety of its citizens, and ruled that the choice of medical alternatives selected from the commercial medical marketplace is not a decision within the zone of constitutionally protected privacy. The California Supreme Court's decision is squarely in line with the holdings of this Court. Since the California

Supreme Court correctly decided the issue, the petition for a writ of certiorari should be denied.

In a series of cases, and on the basis of a variety of theories, this Court has accorded some privacy protection to individual decision making with respect to whether to conceive or to bear a child. (Griswold v. Connecticut (1965) 381 U.S. 479; Eisenstadt v. Baird (1972) 405 U.S. 438; Roe v. Wade, supra, 410 U.S. 113; Doe v. Bolton (1973) 410 U.S. 179; Planned Parenthood v. Danforth, supra, 428 U.S. 52; Carey v. Population Services Int. (1977) 431 U.S. 678.) But, in none of these cases did this Court find that a decision among medical treatments (medical devices, drugs or procedures) fell within the right to privacy, so as to subject state regulation of the available treatment alternatives to constitutional evaluation under a compelling interest test.[1] On the contrary, where a choice of medical alternatives has been involved, this Court has always judged the validity of state regulation under the "rational basis" test.[2] Because California Health and Safety Code section 1707.1, as applied to laetrile, is reasonably related to legitimate governmental purposes -- protection of the public health and protection

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1. Where, as here, the particular choice at issue does not fall within the fundamental right to privacy, a compelling state interest test is not applied. (See, e.g., Carey v. Population Services Int., supra, 431 U.S. 678, 686 (Court applied the compelling state interest test only after concluding that particular decision fell within the right to privacy).)

2. (See, e.g., Planned Parenthood v. Danforth, supra, 428 U.S. 52, 75-79.)

of the public against fraud -- its constitutionality is clear.[3]

In Roe v. Wade, supra, this Court, after an exhaustive review of the medical, religious, and legal history of attitudes toward abortion (410 U.S. at pp. 129-148), concluded that the decision whether to have an abortion fell within the right to privacy (id., at pp. 152-153), and that state regulation of the decision whether to have an abortion could be justified only on a showing of a compelling state interest (id., at p. 155). (See also Doe v. Bolton, supra.) Finding no compelling state interest to justify a total prohibition of the right to decide whether to have an abortion during the first trimester of pregnancy (id., at p. 163),[4] this Court struck down a state statute that prohibited abortions.

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3. This assertion in no way is meant to imply that should, for some reason, this Court choose to apply the compelling state interest test, the statute could not meet that standard as well.

4. Significantly, this Court based its conclusion that a compelling state interest in prohibiting abortions during the first trimester was absent on the fact that "mortality in abortion" during that period "may be less than mortality in normal childbirth." (410 U.S. at p. 163.) While it cannot be claimed that legitimate methos of cancer therapy will be successful in all cases, it is equally clear that delay in seeking such therapy, and avoidance of it altogether, among patients using laetrile for treatment or prevention, has the certain result of increasing cancer mortality. (See, 42 Fed.Reg. at 39769, 39805-39806.) The terms safe and effective, as applied to legitimate cancer therapy, accordingly, are used in a relative sense.

But, notwithstanding the right to privacy found to exist in the general decision whether to have an abortion, this Court also held that there is no privacy right with respect to the choice of a particular medical or surgical procedure by which an abortion may be carried out. This Court held that, after the first trimester ". . . a State may regulate the abortion procedure to the extent that the regulation reasonably relates to the preservation and protection of maternal health." (410 U.S. at p. 163, emphasis added.)[5]

This "reasonable relation" standard is the normal rationality standard that applies to any statute. It is not the "compelling interest" standard that protects the right to privacy. Thus, even though the general decision to have an abortion is within the constitutional protection of privacy, state regulations of particular abortion procedures in the commercial medical marketplace are to be sustained if they reasonably relate to health protection. Such "reasonable regulation," of course, is permissible even where the pregnant woman is fully aware of the risks of late abortion and is willing to take them. Thus,

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5. In Doe v. Bolton, supra, 410 U.S. 179, this Court invalidated a requirement that abortions, unlike other medical or surgical procedures, be performed only at a hospital accredited by the AMA. (Id., at pp. 193-195.) This Court employed a "rational basis" test and found that the AMA accredidation requirement was not "reasonably related" to "the objective the State seeks to accomplish," protection of maternal health, because other "appropriately licensed institutions, satisfy these health interests." (Id., at pp. 194-195.)

the state can protect a pregnant woman's own health even against her wishes (although it cannot prohibit abortions altogether). Indeed, in Roe v. Wade, this Court held that a state, without trenching on any right to privacy, can further its important interests "in the areas of health and safety" by requiring that abortions be performed only at licensed institutions which "insure maximum safety for the patient" and may prohibit any abortion performed by a person not a physician, as defined by state law. (410 U.S. at pp. 149, 150, 165.)[6]

Illustrative of the principle that the choice among medical alternatives incidental to the exercise of some fundamentally protected right is not itself a

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6. If, as the petitioners imply, the constitutional right to privacy attached to all decisions relating to health care, a state could not lawfully require that medical procedures be performed by licensed practicioners only; the licensing requirement, as applied to the provider of medical services, restricts patient options in making health care decisions, just as the prohibition of laetrile under the Health and Safety Code also restricts patient options. It is, of course, well settled, as this Court recognized in Roe v. Wade, supra, that states constitutionally may restrict the practice of medicine to those licensed by state law. (Douglas v. Noble (1923) 271 U.S. 165; Garcia v. Texas State Board of Medical Examiners (W.D.Tex. 1974) 384 F.Supp. 434 (three judge court); England v. La. State Board of Medical Examiners (E.D.La. 1965) 246 F.Supp. 993, aff'd (1966) 384 U.S. 855.) And, the states have broad police powers in regulating the administration of drugs by the health professions. (Robinson v. California (1962) 370 U.S. 660, 664-665; Whipple v. Martinson (1921) 256 U.S. 41, 45.)

decision within the zone of constitutionally protected privacy is this Court's recent holding in Planned Parenthood v. Danforth, supra. There, this Court struck down a state prohibition of a particular abortion procedure, saline amniocentesis. (428 U.S. at p. 79.) However, this Court did not hold that the prohibition violated any right to privacy. This Court also did not hold that because the right to privacy encompasses a woman's decision whether to have an abortion, the state therefore may not prohibit a particular abortion procedure. Rather, citing Roe v. Wade, supra, 410 U.S. at page 164, This Court stated the issue before it as follows: "[W]hether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health.'" (428 U.S. at p. 76, emphasis added.) This Court cited voluminous record evidence of the safety and effectiveness of saline amniocentesis, as compared with other available abortion procedures, and concluded that the state prohibition bore no reasonable relationship to protection of maternal health. (428 U.S. at p. 76.) Significantly, in discussing the validity of the statutory prohibition of this particular medical procedure, this Court did not refer to any constitutional consideration of privacy. No such considerations were involved in the selection of that particular medical procedure by the patient and her physician. The procedure was evaluated by them and by this Court solely on the basis of medical evidence of its safety and effectiveness. (428 U.S. at pp. 75-79.)

Thus, as the California Supreme Court correctly noted,

> "Planned Parenthood thus stands for the proposition that although the decision to have an abortion may be within the constitutional zone of privacy deserving the protection provided by the compelling interest standard, the selection of a particular procedure is a medical matter to which privacy status does not attach and which may be regulated by government, providing a rational basis for such regulation exists." (People v. Privitera, supra, 23 Cal.3d at pp. 703-704 [153 Cal.Rptr. at p. 434; 591 P.2d at p. 922].)

The applicability of these principles to the instant case is clear. An individual is surrounded by a zone of privacy that permits him to make the fundamental decision of whether or not to seek medical treatment for his illness, cancer. However, once the individual has made his decision to seek treatment and ventures into the commercial medical marketplace, his zone of privacy diminishes. The state has the right to impose on that medical marketplace regulations which reasonably relate to the preservation and protection of its citizens. In this case the State of California has required a premarket demonstration of safety and efficacy, for any cancer treatment or cure. Such a state regulation is clearly proper.

The constitutionality of such government premarket regulations has been repeatedly upheld by this Court. (Weinberger v. Hynson, Westcott & Dunning (1973) 412 U.S. 609, 629-630; Ciba Corp. v. Weinberger (1973) 412 U.S. 640, 643-644.) Indeed, just last term this Court upheld the federal premarket requirements of safety and efficacy as applied to laetrile. (United States v. Rutherford (June 18, 1979) 99 S.Ct. 2470, ___ U.S. ___.)

Such food and drug laws are designed to protect "the public health and pocketbook against adulterated and misbranded drugs" and this objective "has led court to declare with

unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes." (United States v. 7 Jugs, etc. of Dr. Salsbury's Rakos (D.Minn. 1944) 53 F.Supp. 746, 752, citing several United States Supreme Court decisions.)

Speaking of the Federal Food, Drug and Cosmetic Act of 1938, this Court observed in United States v. Dotterweich (1943) 320 U.S. 277 at page 280,

> "
> "The purpose of this legislation . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words." (Id., emphasis added.)

The Dotterweich case was cited, quoted from and strongly reaffirmed in United States v. Park (1975) 421 U.S. 658, 668-669.

Thus, there can be no question that the California Supreme Court correctly determined that a premarket demonstration of safety and efficacy for a cancer treatment or cure reasonably relates to the proper goal of preservation and protection of the health of California citizens. Thus, the California Supreme Court's decision was in line with this Court's holdings concerning premarket requirements for drugs as well.

Finally, it should be noted that throughout the petition is the premise that the use of laetrile is harmless and nontoxic. (Privitera Petition, pp. 13, 15, 17.) That

issue was not addressed by the opinion of the California Supreme Court and thus normally will not be reviewed by this Court. (NLRB v. Sears, Roebuck & Co. (1975) 421 U.S. 132, 163-164.) Moreover, as aptly noted by amicus curiae, The American Cancer Society, in its opposition to the petition for a writ of certiorari, such an assertion is simply wrong. (See Amicus Opposition, pp. 12-14.)

CONCLUSION

The sole ground offered by the petitioners for the granting of the petition for a writ of certiorari was an alleged error by the California Supreme Court in construing the decisions of this Court relating to the right to privacy. However, a careful examination of the ruling of the California Supreme Court rendered in the case at bar establishes that that decision is in complete accord with the holdings of this Court. Thus, the decision rendered below is correct, California Health and Safety Code section 1707.1 does not violate any right of privacy protected by the Federal Constitution, and the petition for a writ of certiorari should be denied.

Respectfully submitted,

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FILED
JUL 12 1979
MICHAEL RODAK, JR., CLERK

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On Petition for a Writ of Certiorari to the Supreme Court of California

BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, CALIFORNIA DIVISION, INC., IN OPPOSITION TO THE PETITION FOR CERTIORARI

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SUBJECT INDEX

	Page
Statement of interest of amicus curiae	1
Reasons for denying the petition for writ of certiorari	4
I.	
The California Supreme Court has decided the right of privacy issue in accordance with the applicable decisions of this court	4
II.	
The rationale of the California Supreme Court's opinion is in accord with this court's decision in United States v. Rutherford	9
Conclusion	14

TABLE OF AUTHORITIES CITED

Cases

	Page
Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), cert. den., 414 U.S. 944	13
Eisenstadt v. Baird, 405 U.S. 438 (1972)	9
Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950)	14
People v. Privitera, 23 Cal.3d 697 (1979)	2, 12
Planned Parenthood of Missouri v. Danforth, 428 U.S. 52 (1976)	4, 5
Roe v. Wade, 410 U.S. 113 (1973)	4, 6, 7
United States v. General Research Laboratories, 397 F. Supp. 197 (C.D. Cal. 1975)	13
United States v. Rutherford, ... U.S. ...., 47 U.S.L.W. 4724 (1979)	9, 12, 13, 14
United States v. Spectro Foods Corp., Civ. No. 76-101 (D.N.J.), aff'd in part, rev'd in part, 544 F.2d 1175 (3d Cir. 1976)	13
Whalen v. Roe, 429 U.S. 589 (1977)	4, 8, 9

Constitution

United States Constitution: Fourteenth Amendment	9

Statutes

California Health and Safety Code § 1707.1	3, 8, 14
Federal Food, Drug and Cosmetic Act	9

Other Authorities

	Page
American Cancer Society, 1979 Cancer Facts &Figures p. 9	10
Comment, "Laetrile: Statutory Constitutional Limitations on the Regulation of Ineffective Drugs," 127 U. Pa. L. Rev. 233 (1978)	13
108 Cong. Rec. 3907 (1962)	2
42 Fed. Reg. (1977):	
p. 39767	13
p. 39768	7, 13
p. 39782	7
p. 39797	8
p. 39799	8
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J. S. Mill, On Liberty 100 (Liberty Arts Press 1956)	7
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1962 U.S. Code Cong. & Admin. News, p. 4143	2

In the Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-1850

JAMES ROBERT PRIVITERA, JR.,
Petitioner,

vs.

THE STATE OF CALIFORNIA,
Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of California

BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, CALIFORNIA DIVISION, INC., IN OPPOSITION TO THE PETITION FOR CERTIORARI

STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus curiae is a chartered division of the American Cancer Society, Inc. ("the Society"). Briefly stated the American public and the medical profession rely on the Society, and its 58 chartered Divisions and 2,964 local Units, to provide the most up-to-date and accurate information about cancer. In many cases early and effective treatment of cancer is a life and death matter. One of the major concerns expressed by the public and the medical profession in questions addressed to the Society pertains to unproven

methods of cancer treatment. To respond to the need for information in this area the Society has established a committee on unproven methods and maintains one of the world's largest reference centers for the collection and dissemination of data concerning cancer. To further its obligation to the public and the medical profession to uncover and disseminate the facts relating to unproven methods of cancer treatment, the Society participated as amicus curiae in the proceedings before the California Supreme Court, which resulted in the decision which is the subject of the present petition for writ of certiorari.

Dr. Privitera's petition challenges the existing statutory protection against unproven methods of cancer treatment contained in state and federal drug laws. If the current requirements of safety and efficacy fall, the consumer and the practicing physician will be deprived of the first line of defense against ineffective drugs. It is still true that:

> . . . There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of . . . ineffective drugs.
>
> The physician and consumer should have the assurance from an impartial scientific source that any drug or therapeutic device on the market today is safe and effective for its intended use. . .[1]

The impact of the California Supreme Court's decision, in *People v. Privitera*, 23 Cal.3d 697 (1979), which prevents

[1]Statement by John F. Kennedy to Congress, March 15, 1962, in support of the 1962 Amendments to the Federal Food, Drug and Cosmetic Act. 108 Cong. Rec. 3907; 1962 U.S. Code Cong. & Admin. News at 4143.

circumvention of state and federal drug standards of safety and efficacy by a "right of privacy" rationale, will obviously affect the Society in its role as a primary source of information for the general public and the medical profession for accurate information on unproven methods of cancer treatment.

In sustaining the validity of California Health and Safety Code § 1707.1, the California Supreme Court has effectively closed one of the floodgates that would encourage the marketing of an unproven cancer treatment in California, and elsewhere—the right of privacy rationale. The decision affirms a reasonable pre-market standard. It protects victims of cancer, who when confronted with a life-threatening illness are particularly susceptible to cures promised by use of a worthless, and therefore unsafe and dangerous drug. The Society's interest lies in speaking out for the continuation of the proper balance of manufacturer and consumer interest which currently exists in the statutory scheme regulating drugs. It would be a great disservice to the public if a decision affirming this balanced regulatory scheme was undermined by a petition which, as demonstrated below, is unsound as a matter of law.

REASONS FOR DENYING THE PETITION FOR WRIT OF CERTIORARI

I.

THE CALIFORNIA SUPREME COURT HAS DECIDED THE RIGHT OF PRIVACY ISSUE IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT

The interpretation and application of *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52 (1976); *Roe v. Wade*, 410 U.S. 113 (1973); and *Whalen v. Roe*, 429 U.S. 589 (1977) by the California Supreme Court are squarely in accord with the opinions of this Court. Since lack of accord with the decisions of this Court is the only rationale for review advanced by the Petitioner, the petition should be denied.

The California Supreme Court's decision is in accord with this Court's holding in *Planned Parenthood of Missouri v. Danforth* that choice among medical alternatives is not at this time a decision within the zone of constitutionally protected privacy.[2] There, this Court struck down a state prohibition of a particular abortion procedure, saline amniocentesis.[3] However, the Court did not hold that, because the right of privacy encompasses a woman's decision to have an abortion, the state may not prohibit a particular abortion procedure. Rather, citing *Roe v. Wade, supra,* the Court stated the issue before it as follows:

> "[W]hether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health' ".[4]

[2] 428 U.S. 52 (1976).
[3] *Id.* at 79.
[4] *Id.* at 76.

The Court cited voluminous record evidence of the safety and effectiveness of saline amniocentesis, as compared with other available abortion procedures, and concluded that the state prohibition bore no reasonable relationship to the protection of maternal health. Significantly, in discussing the validity of the statutory prohibition of this particular medical procedure, the Court did not refer to any constitutional considerations of privacy. No such considerations were involved in the selection of that particular medical procedure by the patient and her physician. The procedure was evaluated by them and by the Court solely on the basis of the medical evidence of its safety and effectiveness.

Planned Parenthood thus stands for the proposition that although a decision of whether to have an abortion is within the constitutional zone of privacy, deserving the protection provided by the "compelling interest" standard, the selection of a particular abortion procedure is a medical matter to which privacy status does not attach and which may be regulated by government, provided a rational basis for such regulation exists.

In the instant case, the analogue of the right to decide whether to have an abortion is the right to decide whether to receive or forego cancer treatment. Although the decision whether to receive treatment may be constitutionally protected, the choice among treatment alternatives is not within the scope of the constitutional right to privacy. In *Planned Parenthood* the issue was whether the regulation reasonably relates to the preservation and protection of maternal health. Its analogue here is whether the premarketing provisions of the California statute reasonably

relate to the preservation and protection of the health of the cancer patient. The California Supreme Court correctly held that the state statute establishing a safety and efficacy standard reasonably relates to the preservation and protection of the health of cancer patients.

The decision by the California Supreme Court tracks the rationale expressed by this Court in *Roe v. Wade, supra,* in which this Court recognized that where public health and safety are at stake, even fundamental rights may be regulated and restricted under the state's police power.[5] While finding that the right of privacy is "broad enough to encompass a woman's decision whether or not to terminate her pregnancy",[6] the decision in *Roe* holds that at some point during pregnancy the state's important interest in safeguarding health, in maintaining medical standards, and in protecting potential life became sufficiently compelling to sustain regulation of the factors that govern the abortion decision.[7] With respect to the health of the mother, this Court concluded that the "compelling" point is at approximately the end of the first trimester.[8] This conclusion was based on the medical fact that the risk of a woman's death in first trimester abortions appears to be at least as low as that in normal child birth, while the increase in the hazards to abortion procedure in the second trimester justified imposition of state regulations. With respect to the state's interest in potential life, the compelling point was found to be at viability—which occurs approximately at the end of the second trimester. At this point this Court indicated that the state could even prohibit abortion except when necessary for the preservation of maternal life or health.[9]

[5] *Roe v. Wade,* 410 U.S. at 153-154, 162-163.
[6] *Id.* at 153.
[7] *Id.* at 154.
[8] *Id.* at 163.

These aspects of the holding in *Roe* are significant in light of the constitutional issue raised, for they reflect this Court's recognition of the government's compelling interest in protecting individual health, and in protecting the public health generally where individual conduct may adversely affect the well-being of others.[10] The authority to protect individual health, and the public health generally, may be exercised to overrule the woman's personal decision to undergo a particular medical or surgical procedure during the second and third trimesters of pregnancy even when she is fully aware of the risks of the procedure, and is willing to take those risks.[11] An individual's decision to use Laetrile can stand on no higher constitutional level than the decision of a woman to have an abortion in the later stages of pregnancy.

It has been established that a significant number of cancer patients can be cured or have their lives extended by the use of legitimate therapy, especially when treatment is begun as soon as possible after diagnosis.[12] The availability of Laetrile serves to encourage delay among

[9] *Id.*
[10] Even John Stuart Mill recognized that state regulation in the area of public health did not impermissibly infringe upon the choice of the individual. He contended that where, "there is a definite damage, or a definite risk of damage, either to an individual or to the public, the case is taken out of the province of liberty and placed in that of morality or law." J. S. Mill, On Liberty 100 (Liberty Arts Press 1956).
[11] 410 U.S. at 162-165.
[12] *E.g.,* The FDA rulemaking decision on laetrile, *Laetrile, Commissioner's Decision,* 42 Fed. Reg. 39768, 39782 (1977).

certain cancer patients in seeking effective therapy.[13] Moreover, even among patients who begin treatment of their cancers with effective therapy, the readily acknowledged side effects of that therapy may cause them to cease to use such methods at a time when their application still may be successful, and turn instead to Laetrile—"a painless cure".[14] Because legitimate therapy may be stopped, delayed or avoided, many cancer patients will die needlessly or prematurely. This fact alone provides compelling justification for prohibiting interstate transportation and sale of drugs such as Laetrile absent compliance with the premarketing standards that are contained in federal drug laws and California Health and Safety Code § 1707.1.

Finally, the California Supreme Court's decision closely tracks the state interest rationale set forth by this Court in *Whalen v. Roe, supra.* There, the Court upheld a state statute requiring physicians to report the names and addresses of patients for whom the physicians had prescribed certain dangerous drugs to a state agency. The patients contended, among other things, that the statute invaded their constitutionally protected zone of privacy by depriving them of the right to decide independently, with the advice of a physician, to acquire and use needed medication. The Court upheld the statute, citing cases using ordinary, not "compelling interest" tests for the exercise of the police power and concluded that the impact of the statute on either the reputation or the independence of patients for whom the specified drugs are medically indicated is not sufficient to constitute an invasion of any right

[13] *Id.* at 39799.
[14] *Id.* at 39797, 39799.

or liberty protected by the Fourteenth Amendment.[15] The Court also held that the physicians' claim is derivative from the patients' and must therefore fall along with the rejected patients' claim of protection.[16]

Furthermore, although the drugs involved in *Whalen* were narcotics and classified as dangerous drugs, they were safe and effective for their intended use by FDA standards. Thus they satisfied the standards which Dr. Privitera has tried to circumvent. To the same effect is *Eisenstadt v. Baird,* 405 U.S. 438 (1972), where this Court held that unmarried individuals have a privacy right to purchase and use contraceptives, but noted that the contraceptives themselves, if they are new drugs within the meaning of the Federal Food, Drug and Cosmetic Act, would be subject to pre-market approval and the safety and efficacy standard. Thus, the physician-patient relationship language of *Whalen* relied on by Petitioner is inapplicable. In *Whalen* the drugs had passed the safety and efficacy threshold and were "approved". The present case is distinct, as Laetrile has not been found safe or effective by the appropriate agency.

II.

THE RATIONALE OF THE CALIFORNIA SUPREME COURT'S OPINION IS IN ACCORD WITH THIS COURT'S DECISION IN UNITED STATES V. RUTHERFORD

This Court in *United States v. Rutherford,* ..... U.S. ....., 47 U.S.L.W. 4724 (1979), expressly held that the federal drug law standards of safety and efficacy, which corre-

[15] 429 U.S. at 603-604.
[16] *Id.* at 604.

spond with the California statutory provisions, bear a reasonable relationship to the terminal patient, which is the context on which most cancer patients are viewed by the general public.[17]

> . . . Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs.
>
> A drug is effective within the meaning of § 201(p)(1) if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces the results claimed for it under prescribed conditions. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S., at 629-634; n. 7 *supra*. Contrary to the Court of Appeals' apparent assumption, see 582 F.2d at 1236, effectiveness does not necessarily denote capacity to cure. In the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain. See 42 Fed. Reg. 39776-39786.

[17]This popular belief contrasts strongly with the actual statistics relating to survival from cancer due to earlier diagnosis and the steady improvement in surgical, x-ray and chemical approaches to the management of cancer. In the 1900's few cancer patients had any hope of long-term survival. In the 1930's less than one-in-five were alive at least five years after treatment. In the 1950's it was one-in-four. Now the ratio of patients alive after five years of disease is one in three. With even earlier diagnosis and proper treatment, half of those who have cancer could be saved. See American Cancer Society, *1977 Cancer Facts & Figures*.

The importance of early detection and treatment in terms of survival when cancer is localized as opposed to delay in treatment until the cancer has spread is set forth in the American Cancer Society, *1979 Cancer Facts & Figures* at page 9. The chart shows the following five year survival rates for localized as compared to disseminated cancer: bladder 72/14; breast 85/47; colon-rectum 71/26; larynx 79/32; lung 33/4; oral 67/25; prostate 70/35; uterus-cervix 78/37; and uterus corpus 86/33.

> So too, the concept of safety under § 201(p)(1) is not without meaning for terminal patients. Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. . . .
>
> Moreover, there is a special sense in which the relationship between drug effectiveness and safety has meaning in the context of incurable illnesses. An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. See 107 Cong. Rec. 5640 (1961) (comments of Sen. Kefauver). But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible. . . .
>
> . . . To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including lineaments of turpentine, mustard, oil, eggs, and ammonia; peatmoss; arrangements of floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil and suet. . . .
>
> We note finally that construing § 201(p)(1) to encompass treatments for terminal diseases does not

> foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. Section 505(i) of the Act, 21 U.S.C. § 355(i), exempts from premarketing approval drugs intended solely for investigative use if they satisfy certain preclinical testing and other criteria . . .[18]

Thus this Court in *Rutherford,* construing a statute which provides the same protection as the California statute, found a reasonable relationship between the protections provided and the cancer patient. The California Supreme Court's application of the reasonable relationship test is in accord with the decision in *Rutherford.*

Petitioner argues that Laetrile is not toxic[19] and is harmless when used by cancer victims.[20] Apparently petitioner is arguing that Laetrile is safe and/or effective. However, the issue of Laetrile's safety or efficacy was specifically not addressed by the California Supreme Court.[21] The issue decided by the California Supreme Court was whether the statutory scheme establishing a standard of safety and efficacy is a reasonable exercise of the police power.

While it is not an issue properly before this Court, amicus curiae cannot overlook the false premise advanced in the petition that Laetrile is not toxic. In reality the great weight of authority is to the contrary. Medical re-

[18]Slip opinion at pp. 10-13, 47 U.S.L.W. at 4727-4728.

[19]Petition for Writ of Certiorari at 12, 22.

[20]*Id.* at 13, 15 and 17.

[21]*People* v. *Privitera,* 23 Cal.3d at 708.

searchers,[22] courts,[23] and the Food and Drug Administration[24] have all gathered evidence of Laetrile's toxicity.

The petitioner also argues that Laetrile is a "less hazardous" treatment than conventional cancer therapy, and in effect that it is harmless when used by cancer victims, and therefore less regulation is permissible since the treatment itself is not harmful.[25] This overlooks the rationale underlying the safety and efficacy requirements of state and federal law. Where drugs utilized for life-threatening illness are involved, safety is equated with efficacy because the treatment of a life-threatening illness with an ineffective drug may delay the initiation of effective therapy until the disease is beyond control. *Durovic v. Richardson,* 479 F.2d 242, 250 (7th Cir. 1973), *cert. den.,* 414 U.S. 944. As this Court stated in *United States v. Rutherford, supra:*

> ". . . An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect (Citation omitted.) But if an individual suffering from a potential fatal disease rejects conventional therapy in favor of a drug with no demonstrable

[22]*E.g.,* Lewis, "Laetrile", 127 Western Journal of Medicine 55 (July, 1977); Jukes, "Laetrile for Cancer", 236 Journal of the American Medical Ass'n. 1284 (Sept. 13, 1976); Hambert, "Fatal Cyanide Poisoning: Accidental Ingestion of Amygdalin", 238 J. AMA 482 (Aug. 8, 1977); Smith, et al., "Laetrile Toxicity: A Report of Two Cases", 238 J. AMA 1361 (Sept. 13, 1976). *See also,* Comment, "Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs", 127 U. Pa. L. Rev. 233, 246-249 (1978), and materials cited.

[23]*United States v. General Research Laboratories,* 397 F. Supp. 197, 198-199 (C.D. Cal. 1975) (toxicity); *cf. United States v. Spectro Foods Corp.,* Civ. No. 76-101 (D.N.J.), *aff'd in part, rev'd in part,* 544 F.2d 1175 (3d Cir. 1976) (adulterated and misbranded).

[24]42 Fed. Reg. 39767, 39768 (1977).

[25]Petition for Writ of Certiorari at 15, 17.

curative property the consequences can be irreversible . . ."[26]

Thus, the decision by the California Supreme Court is in accord with prior decisions of this Court. To the extent the petition attempts to raise the issue of whether Laetrile itself is safe or effective in treating cancer, it misconstrues the issues before this Court.

CONCLUSION

The California Supreme Court's interpretation of Health and Safety Code § 1707.1 is consistent with the opinions rendered in analogous cases by this Court. The decision by the California Supreme Court is in keeping with the principles enunciated by this Court, and reinforces the protections provided by state and federal law for patients with life-threatening illness. For these reasons, Dr. Privitera's petition should be denied.

Dated July 11, 1979

Respectfully submitted,

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[26]Slip Opinion at 11; 47 U.S.L.W. at 4727. See Justice Douglas' opinion in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599-600 (1950) ("[Congress] may conclude . . . that public damage may result even from harmless articles if they are allowed to be sold as panaceas for man's ills . . .").